USE OF ACTIVITY THEORY AS BASIS FOR A NOVEL NEEDS-FINDING TECHNIQUE FOR MEDICAL DEVICE DEVELOPMENT IN LOW-RESOURCE ENVIRONMENTS

by

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B.A.Sc, The University of British Columbia, 2013

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF

THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF APPLIED SCIENCE

in

THE FACULTY OF GRADUATE AND POSTDOCTORAL STUDIES

(Biomedical Engineering)

THE UNIVERSITY OF BRITISH COLUMBIA

(Vancouver)

April 2017

Abstract

According to the World Health Organization, appropriate medical devices are not sufficiently available in low-resource environments within low and middle income countries. Lack of systematic structures, challenges with entering existing markets and incomplete understanding of design needs within these contexts are the key reasons for this problem. It is challenging to understand the needs for medical device development in low and middle income countries because the problem space has complex socioeconomic, political, technical and clinical constraints to navigate. Existing needs-finding techniques for engineering design do not provide an explicit means of identifying and synthesizing these complex factors. The main contribution of this thesis is development of a novel needs-finding technique for medical device development, specifically for low-resource environments. The proposed novel technique is empirically compared to the needs-finding technique of the well-established Stanford Biodesign Process.

In a series of studies, the Activity Theory-based Needs-finding Technique (ATNF), based on Activity Theory, was integrated into the engineering design process. The cultural historical Activity Theory, rooted in Russian psychology, provides a framework for analyzing human activity and social structures. The ATNF proposes a modified activity system that explicitly situates technology within an activity. Mapping activities and identifying tension points within them allow for a fuller understanding of design needs. The ATNF method was initially investigated through its detailed application on a case study in the field of health technology development in low-resource environments. Thereafter, an ethnographic comparative study was completed to investigate the ATNF technique and the Biodesign technique by examining the differences between the needs statements and the process of developing them.

The results indicate that the novel ATNF method is more effective in identifying an appropriate scope and desired change. However, the design artefacts from the ATNF and the Biodesign techniques equally cover socioeconomic, clinical and technical issues. This suggests that the strength of the ATNF technique is in creating connections between issues to develop an appropriate scope and in identifying desired change. The research supports that the ATNF technique is a viable needs-finding method and that it has particular strengths that could be leveraged for medical device development in low-resource environments.

Preface

This thesis is submitted in partial fulfillment of the requirements for the degree of Master of Applied Science in Biomedical Engineering at the University of British Columbia.

A summarized version of the content in Chapters 2 and 3 of this thesis has been published in the Proceedings of the IEEE Engineering in Medicine and Biology Conference 2016. The first author was responsible for conducting the literature review, developing the new needs-finding technique, applying it on a case study and writing the manuscript. This paper has two co-authors, Dr. Ratto and Dr. Van der Loos. They provided feedback on development of the novel needs-finding technique and the manuscript.

> S. Rismani, M. Ratto and H. F. M. Van der Loos, "Use of activity theory-based need finding for biomedical device development," *Proceedings of the 2016 38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*, Orlando, FL, 2016, pp. 4341-4344.

An overview of the study presented in Chapters 4 and 5 of this thesis has been submitted to International Conference of Engineering Design 2017 and is currently under review. The first author was responsible for designing the study, the data analysis and writing the manuscript. The co-author, Dr. Van der Loos, provided feedback on the manuscript. Two co-op students, Renee Bernard and Candice Ip, assisted with the qualitative data analysis for this paper.

> S. Rismani, and H. F. M. Van der Loos, "Improving Needs-finding techniques for medical device development at low resource environments using Activity Theory," *2017 International Conference on Engineering Design (ICED)*, Vancouver, Canada, 2017.

Aside from the above publications the author was involved in the publication of two other conference papers that motivated the work done for this thesis.

S. Rismani, and H. F. M. Van der Loos, " The competitive advantage of using 3d-printing in low-resource healthcare settings," *Proceedings of the 2015 International Conference on Engineering Design (ICED)*, Milan, Italy, 2015.

S. Rismani, G. Allan, V. Chung, D. Wilson, " Applying the biodesign innovation process: Addressing the inadequate supply of surgical screws in the developing world," *Proceedings of the 2014 IEEE Conference on Healthcare Innovation and Point-of-Care Technologies*, Seattle, DC, 2014.

All human-subject experiments described in this thesis were approved by the University of British Columbia Behavioural Research Ethics Board (H12-01640).

Table of Contents

List of Tables

List of Figures

Acknowledgements

I would like to thank my supervisor, Dr. Machiel Van der Loos, for guiding me throughout my search for a research topic and development of this work. His patience, openness to new ideas, knowledge and wisdom has allowed me to learn how to “dance with ambiguity” and develop professionally and personally throughout this time at UBC.

I would also like to thank Dr. Elizabeth Croft for her continued support throughout my time at the CARIS lab, Dr. David Wilson, for his support of working with the Engineer-in-Scrubs students, Dr. Matt Ratto, for his help in creating a connection with the CoRSU hospital and providing advice on theory development and Dr. Anthony Hodgson for his continued support, specifically during the ICED 2015 conference.

I would like to thank the Engineers-in-Scrubs program and Natural Sciences and Engineering Research Council (NSERC) for supporting this work financially. I am also indebted to the staff at the CoRSU rehabilitation hospital, the orthopaedic ward staff at the Mulago National Referral hospital, the program coordinator (Nathan O’Hara) and clinicians of the USTOP program for guiding me throughout my trip in Uganda and answering all of my questions.

This research would have not been possible without the participation of the students from the 2015-16 Engineers-in-Scrubs cohort and the Biomedical Engineering Steam Team. I am grateful for their participation and collaboration throughout this process.

This work is inspired by all the great work ethic and spirit of my colleagues at the CARIS lab. Specifically, I would like to thank AJung Moon and Navid Shirzad, for editing this thesis, their mentorship and friendship, Philip Wang and Mahsa Khalili, for their advice and friendship, Solange Cevat for thinking through Activity Theory with me, Candice Ip and Renee Bernard for coding part of my data. Also, I would like to thank Florin Gheorghe, who inspired me to pursue research in design methodology and provided valuable feedback at critical times.

I would like to thank my dance group members (Ghazal, Nasime, Elmira, Shanli, Samineh, Shailin and Bahar) for keeping me dancing throughout this time and my friends (Marianne, Kenard, Rebeca, Tim and Asal) for their continuous encouragement through laughter.

Finally, I would like to thank my parents, Nazila and Reza, my brother, Araz and my sister-in-law, Mahsan, for their patience, kindness and for keeping me grounded and inspired throughout this process.

Chapter 1: Introduction

Despite the recent increased focus on medical device development, there is a great disparity between the availability and accessibility of medical devices in High Income Countries (HIC) versus Low and Middle Income Countries (LMIC) [1], [2]. The lack of appropriate medical devices in LMIC is one of the factors that is contributing to the inadequate delivery of care in these settings [1], [2]. Why is there such a significant gap between the availability of appropriate medical devices in HIC versus LMIC? What is the role of engineering companies in addressing this gap? Can improvements in medical device development methodology help in closing this gap? If so, how? These are some of the central questions explored in this thesis. Existing research and development on design methodology for medical device development for LMIC is sparse. This thesis proposes and evaluates a novel needs-finding tool that aims to help engineering design teams improve their understanding of their problem space and develop need statements that synthesize socioeconomic, political, clinical and technical issues present in medical device development for LMIC.

1.1 Motivation: making medical devices equally accessible globally

Medical technology is one of the six essential building blocks of a well-functioning healthcare system as identified by WHO [3]. The gap in the availability and accessibility of appropriate medical technologies between HIC and LMIC is one of the contributing factors to the current global burden of disease[1] LMIC face. According to a WHO report, in 2004Africa and south Asia counted for 40% of the global population but had 54% of the global burden of disease[3]. On the other hand, the investments and developments in healthcare technology show a reverse trend. The Global Forum of Health Research estimated that 97% of global spending on health research and development was within the HIC healthcare market and only 3% was spent by LMIC [3]. The level of spending on research and development of healthcare technology is significantly higher in HIC as opposed to LMIC. Lack of appropriate resources for medical device development for LMIC creates a negatively impacts the quality of care delivered to patients in LMIC.

[1] The global burden of disease is a major determinant of how World Health Organization (WHO) assesses the healthcare needs across countries. WHO measures the global burden of diseases using Disability Adjusted Life Years (DALY), “a time-based measure that combines years of life lost due to premature mortality (YLL) and years lived with a disability (YLD)”[3].

Recognizing the need to change, in 2007 the World Health Assembly (WHA) resolutions on health technologies and primary health care reform announced the development of appropriate health technologies as an area of focus for improving delivery of care globally [4], [5]. The Global Health Technology Initiative was shaped around the same time with two main objectives: to assist countries to establish healthcare frameworks and to encourage more innovation in health technologies for LMIC [3]. Therefore, there is need to investigate, develop and report frameworks and medical device development processes that are appropriate for healthcare systems in LMIC.

1.1.1 Status quo for Medical Device Development in HIC versus in LMIC

Medical device development is a well-established process within HIC. The medical device industry has grown significantly as physicians, government and investors started to realize the positive impact that healthcare technology can have in improving delivery of care, outcomes and cost. This has led to HIC creating appropriate political structures, monetary incentives, and regulatory systems to ensure that medical devices can be created, used and maintained safely where necessary. The Stage-Gate process, illustrated in Figure 1-1, outlines the general steps for development of medical devices for use in a healthcare setting in HIC [6], [7].

Figure 1-1 The Stage-Gate Process for Medical Device Development

This development process operates within a network of stakeholders including the government, major corporations, small companies, regulatory bodies, healthcare centers, clinicians and the public. Most of the major medical device corporations and companies are based in HIC. Since most medical devices have been primarily developed in HIC, they are also designed for this context [1]. Appropriate medical devices are widely accessible to stakeholders in need, and there is a continuous effort in furthering development in HIC.

On the other hand, physicians and healthcare centres in LMIC often have a different approach to obtaining the necessary medical devices than that of HIC. The majority of medical devices in

LMIC are either purchased from major companies in HIC or donated from various organizations globally [2], [3]. There are minimal local development and manufacturing resources in LMIC [2], [3]. Additionally, healthcare organizations in LMIC do not follow strict regulatory guidelines for obtaining or maintaining medical devices, and the governments in these countries often do not have a lot of resources dedicated toward monitoring and evaluating medical devices. The result is a graveyard of unused medical devices and a lack of appropriate equipment when needed[5]. The WHO and the international medical community recognize the need for the further development of appropriate medical devices for LMIC. In the past decade, there has been a more concentrated effort in improving the process of medical device development in LMIC [5].

1.1.2 Challenge: low-resource settings still do not have access to appropriate equipment

Healthcare centres and physicians at LMIC often do not have access to appropriate medical devices. This ultimately impacts the quality of care and lives of patients. The WHO identified three main factors that contribute to this problem, and these are explained in the following sections [3].

1.1.2.1 Healthcare system level considerations

A specific structure is necessary to ensure that medical devices are acquired, used and discarded appropriately. This structure is often established by federal and regional governments. Appropriate regulatory bodies are necessary to ensure that medical devices are evaluated at both a national and an organization level. The FDA (Food and Drug Administration) and Health Canada are the two federal regulatory bodies in the United States and Canada, respectively. European Commission also has specific regulatory framework for medical device development within European countries. The necessary regulatory structure exists within HIC; however, it is not fully realized in LMIC. According to the WHO, only a third of LMIC have some form of regulatory standards [3]. With these systems lacking, medical devices are brought into many countries with no monitoring of its need or safety for a specific context. This can have severe consequences for all the stakeholders within the healthcare system. The WHO and other international organizations recognize this issue and are developing best practices guidelines [8], [9].

1.1.2.2 Market conditions and financing

Both financing and market conditions heavily influence whether healthcare centres can afford to purchase and maintain medical devices. In addition, these factors influence the local medical device development industry. Historically, the majority of investments in the research and development of medical devices has been concentrated in HIC. In addition, healthcare centres in these countries generally have a larger budget for purchasing medical devices. However, after the WHA resolution, more focus has been placed internationally and locally on creating a necessary monetary condition to bring appropriate medical devices into healthcare centres in LMIC. Large corporations have started realizing the market potential in LMIC. More investment and philanthropy opportunities exist for the development of medical devices for LMIC. The E-health movement and lower cost of advanced technology have also made it possible to develop more affordable and appropriate solutions for LMIC. It is still challenging for engineering companies to find the necessary financial investment for developing medical devices for LMIC. However, the cost of technology is decreasing, and more financial resources are currently available.

1.1.2.3 Lack of understanding of needs for LMIC

More companies are focusing on developing medical devices for LMIC; however, it is more difficult for designers to create for the low resource environment because they are not as familiar with the design context. WHO, the United States Agency for International Development (USAID), and other international organizations have recognized that needs are not appropriately understood in healthcare settings in LMIC [1], [2], [10], [11]. According to the "Idea to Impact" report by USAID, the scale-up time (i.e., the time it takes to go from one initial prototype to having the devices disseminated where needed) is significantly higher in LMIC compared to HIC. The "Idea to Impact" guidelines identify that most companies do not have a comprehensive understanding of their problem space and that scale-up time could become shorter if design teams have a more holistic approach to needs finding [10]. Existing design methodologies have been primarily developed for design in HIC. There has only been a limited amount of work done in developing these appropriate techniques for LMIC. The existing methodologies and their shortcomings are discussed in Section 2.1.

1.2 Proposing and evaluating a new need-finding technique

This thesis explores and addresses the challenge of understanding design needs for medical device development in LMIC. Issues mentioned in Sections 1.1.2.1 and 1.1.2.2 are outside of the scope of this engineering design thesis. However, all design processes start with a needs-finding stage, and the author proposes and demonstrates the applicability of a new needs-finding technique based on Activity Theory in Chapter 3. This novel technique aims to provide the designer with a way of incorporating social, economic and political factors alongside the clinical and technical aspects necessary for a design challenge. The hypothesis of this thesis is that the Activity Theory-based Needs Finding (ATNF) technique allows design teams to achieve an enriched understanding of their design problem and develop need statements that are more comprehensive and inclusive of the socioeconomic, clinical and technical factors. The ATNF technique is compared against a more conventional needs-finding technique within a series of design workshops with biomedical engineering student teams. Chapters 4 and 5 highlight the methods and results of this study.

1.3 Overview of Thesis

The main contributions of this thesis are (1) a new needs-finding technique based on Activity Theory for the development of medical devices and (2) evaluation of this technique in comparison to a conventional needs-finding technique. The observed shifts on how design teams approached the problems can motivate further research in design methodology for medical device development in LMIC.

The following describes the outline of this thesis:

Chapter 2 provides a background of medical device design and the existing design techniques that are used to identify needs. The chapter then reviews the shortcomings of these techniques and follows by providing an overview of existing theories on the role of technology in society, specifically expanding on Activity Theory and why it is used as the basis for this new needs-finding technique.

Chapter 3 introduces and describes the novel Activity Theory Needs Finding (ATNF) technique, developed by the author. The new design technique is initially verified by applying it to a relevant health technology project in LMIC.

Following the initial case study, the author conducted a comparative study with biomedical engineering student design teams to evaluate how the teams that use the ATNF technique performed compared to a conventional need finding technique (Chapter 4). The results of analysis from this study are presented in Chapter 5. The following chapter includes a discussion of the findings and provides a more refined account of the ATNF Technique based on the study (Chapter 6).

Chapter 7 concludes this thesis by providing a summary of the research work and outlining possible areas for future work.

Chapter 2: Background – Needs Finding in the Biomedical Device Design Process

This chapter provides an overview of the most prominent design tools that are used in defining user needs and inputs, outlines the shortcoming of these techniques for medical device development in LMIC and discusses the potential theories that could offer an alternate and improved perspective for developing need statements.

2.1.1 Product development, engineering design and needs finding methods

The terms *product development* and *engineering design processes* are often used interchangeably in the literature. Ullman defines product or engineering design process in a simple form as illustrated in Figure 2-1 [12]. The process is iterative in nature and it starts with product definition and ends with the retirement of the product. This definition is synonymous with that of product development processes [13]. The main focus of this thesis is on the product definition stage. During the product definition stage, the design team defines the attributes of a product based on their understanding of the problem space. Other design methodologies such as the Biodesign process use the term *needs finding* instead of product definition [14]. Needs finding is a process for understanding the unmet needs of potential customers within a certain context. This thesis uses *needs finding* and *product definition* interchangeably.

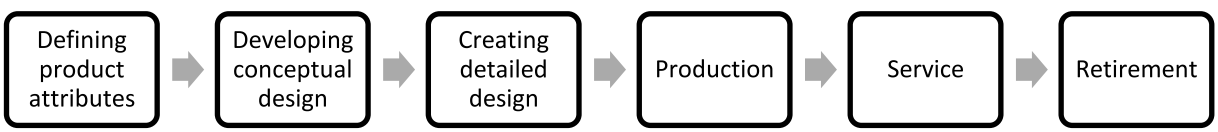

Figure 2-1. Product Development Process [12]

Engineering design methodologies continuously change through design research and practice [15]. A review of design methodology literature for medical device development reveals three main groups: classical systematic approaches, human-centred design, and context appropriate design. The next sections will outline the most common engineering design processes for medical device development and highlight the techniques used during the product definition stages. Each section notes the advantages and disadvantages of these techniques.

2.1.2 Classical medical device design

Classical medical device design processes are part of "first generation" design methodologies initially developed in 1960s and 70s[15]. These methodologies allow engineering teams to systematically break down a complex problem into smaller pieces [15], [16]. There are many different "first generation" design methodologies used for medical device development. FDA regulatory standards reference the waterfall model[2] [17] and concurrent engineering[3] [18]. Systematic design methodology by Pahl and Beitz is recognized as one of the best systematic design practices [19]. Although each one of these processes uses different terminology, they have similar underlying principles and structure. This section focuses on describing the systematic design methodology and its approach to needs finding.

Systematic design methodology has four main stages, as illustrated in Figure 2-2. An engineering team goes through conceptual design, embodiment design, detailed design and prototype manufacturing iteratively [16], [19]. Needs and requirements are primarily defined in the conceptual design stage. Interviews with the primary customers, review of existing literature and benchmarking are the core methods that engineering teams use to gather information about their design problem and understand customer needs. Thereafter, functional analysis[4], attribute listing[5] and Quality Function Deployment (QFD)[6] are three of the main techniques used to develop a comprehensive list of design requirements. These techniques allow teams to connect customer needs to requirements.

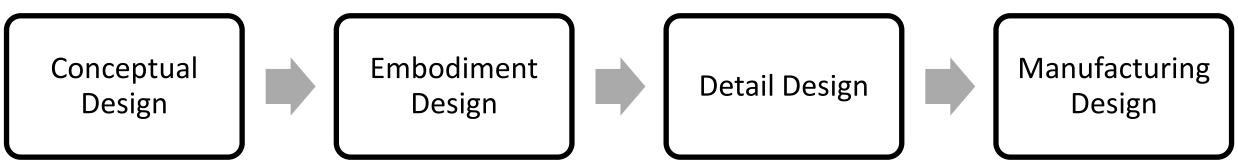

Figure 2-2 Systematic Design Process Model [19]

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[2] The Waterfall Model is a traditional and sequential product development process that starts with defining requirements, designing a device, evaluating based on the requirements and finally manufacturing the device [17].
[3] Concurrent engineering emphasizes involvement and contribution of various parties in the design process including the production staff and the clinicians [17], [18].
[4] Functional analysis identifies all the necessary functions that the product needs to accomplish [16].
[5] Attribute listing breaks down the desired qualities and features of a product [16].
[6] Quality Function Deployment is a systematic way of mapping customer needs to technical specifications[16].

Systematic design methodology focuses primarily on developing technical requirements for a device based on information gathered from customer interviews and literature review. Many medical devices used today are initially designed with this approach. The advantage of systematic design methodology is that it provides the engineering team with techniques for defining a set of technical design requirements. However, the methods used in the conceptual design stage do not provide a comprehensive framework for identifying, collecting and synthesizing information about the socioeconomic, clinical and technical factors in the problem space. If the design space has changing and unknown socioeconomic, clinical and technical factors, the systematic design methodology does not have means of identifying and integrating those to design specifications. Due to the history of medical device development and existing systematic infrastructure in medical device industry in HIC, socioeconomic, clinical and technical factors are more defined and well-understood compared to that of LMIC [1], [3]. Even though systematic design methodologies have been executed effectively in most of the medical device development cases in HIC [16], they are not sufficient for conducting a comprehensive analysis of needs that exist within less defined medical device design spaces in LMIC.

2.1.3 Human, user, and patient centred design

Human centred design (HCD) techniques are sometimes referred to as "second generation" design methodologies, in which more focus was placed on involving the user in the design process [15]. HCD methodologies emerged in the late 1970s and 1980s when designers noticed that existing design techniques did not account for how a product would be adopted and used by people [15]. The HCD techniques build on the basic principles of participatory design[7]. The terms "user centred design" and "patient centred design" are often used synonymously to human centred design.

Human centred design methodology has been used by many different researchers and companies for medical device development [20]–[22]. The IDEO toolkit outlines three main stages of the HCD process, which are "Hear", "Create" and "Deliver"[23]. Needs finding occurs mainly in the "hear" phase. The objective of the design team in the "hear" phase is to be immersed within the context of the stakeholders and through that understand their needs. The toolkit suggests many different needs-finding methods including immersive field observations, in-depth expert

[7] Participatory Design (PD) encourages active involvement of the user in development and assessment of a particular product [83].

interviews, ethnographic research, and development of personas, profiles and frameworks [23]. Today, human centred design techniques are taught in many medical device development programs and are applied widely by many medical device companies and researchers.

The HCD method offers many advantages to the field of medical device development because it provides the tools to gather information from various stakeholders and to create corresponding frameworks. Literature and practice show that HCD does result in good quality design for medical devices both in HIC [24], [25] and LMIC [10], [26], [27]. However, design practitioners have highlighted shortcomings of HCD [28] . The primary focus of needs finding in HCD is on the users. HCD methodologies assume that a thorough analysis of multiple stakeholders lends to a complete understanding of the context. However, medical devices are designed to be part of a specific clinical intervention (i.e., an activity). Understanding the users in this intervention only provides a partial perspective of the activity and its context. The design team does not explicitly consider how a specific intervention is situated in a larger socioeconomic context and how that effects the design needs. This shortcomings of HCD have been shown in practice. In 2010, Design that Matters starting working on the problem of keeping babies warm after birth in developing countries. Expert designers from various backgrounds followed HCD techniques to fully understand the needs of the primary users, nurses and doctors. They developed the NeoNurture incubator, which was internationally recognized. However, the incubator never went into production because the manufacturers did not accept the risk of entering this new market. Even though, the design team had diligently followed the HCD process, they had not considered the needs of the stakeholders (i.e., manufacturers, government officials) within the larger ecosystem [10], [29].

2.1.4 More context aware methodologies

Recently, there has been a shift within the design literature toward methodologies that focus more on considering context for medical device design. The Biodesign process, idea-to-impact toolkit, context-aware design, system thinking and value driven innovation are some of the most prominent methods, and are described below.

The Biodesign processes takes on a need driven innovation approach and emphasizes understanding problems and needs of various stakeholders [14], [30]. The Idea-to-impact toolkit is published by USAID in collaboration with a number of leaders in medical device development for LMIC. The toolkit offers a framework and specific techniques to get a product from an idea stage to scale-up [10]. Context-aware design is applied differently across various projects. The main idea is that the design team needs to understand the contextual factors and how they interact with specific stakeholders [31], [32]. System thinking is a framework designed to analyze social structures, and more recently some companies have applied it to medical device development. The primary principles are to understand various systems required for a device to function and how they connect to each other [33]. Finally, value driven design is also investigated by various researchers, and the main idea is to understand the values of different stakeholders and consider them for design of a medical device [34]. All of these methodologies have stemmed from the practice of medical device development in HIC and LMIC. They highlight what has worked and does not work in practice. However, the author has not found any studies on the effectiveness of these techniques in capturing contextual factors in design of medical devices for HIC or LMIC.

2.2 Developing an alternate needs-finding technique

There is a great demand for developing appropriate medical devices for LMIC [5] . It is challenging to understand design needs for medical device development (MDD) in LMIC because the context in LMIC is diverse and complex[35]. The existing needs-finding techniques in MDD have evolved to allow engineering teams to develop products that have a sustainable impact. However, as highlighted in Section 2.1, existing needs-finding methodologies do not provide a theoretical framework to comprehensively account and synthesize the socioeconomic context of design along with the clinical and technical factors. In addition, since medical device development has been mostly done in HIC, most of the design methodology research has been focused on HIC [1]. The author proposes a novel needs-finding technique for medical device development in LMIC based on Activity Theory. The remaining sections of Chapter 2 provide a summary of the background literature that was used to develop the novel technique. Chapter 3 outlines the new needs-finding technique and provides an example of its application.

2.2.1 Current theories in technology and society

Many designers and researchers in the field of MDD for LMIC need to design for a specific context. However, how should a design team go about defining and understanding context? This section provides an overview of four main theories on understanding socio-technical context. These are Actor Network Theory (ANT), distributed cognition, ethnomethodology and Activity Theory (AT). Section 2.2.2 describes the motivation for using AT as the guiding framework for developing a novel needs-finding technique.

2.2.1.1 Actor-Network Theory

Actor-network theory (ANT) was developed in the mid 1980s by Brano Latour, Michel Calllon, and John Law. ANT provides a framework for studying sociotechnical processes. Two important elements of this theory are actants and their networks. Actants, also referred to as actors, are any medium, individual or collective (human or non-human) that have the agency to associate themselves with other actants in a network. Actants, their interests and their relationships with other actants creates a network that allows various actants to reach their interests. ANT investigates how actants change within a network and how the network changes in return. ANT acts on the three main principles of agnosticism, generalized symmetry, and free association. Agnosticism emphasizes abandonment of any assumptions when analyzing a socio-technical system. Generalized symmetry defines a symmetrical existence for technology, humans, and society. That means that ANT does not distinguish between an object, a human or an organization. Finally, the free association states that there is no difference between natural and social events. ANT users apply different interpretations of the theory. ANT has been used to describe the design process of new technologies and how networks change with the introduction of various actants. The theory also promotes a more comprehensive understanding of social, political and technical parameters involved in the development of new technology [36]–[39].

However, there are two main concerns when considering ANT for use as a need-finding tool for medical device development in LMIC. Firstly, ANT is most suitable for retrospective studies of technology implementation. It does not offer any theoretical means of investigating change and needs within a specific context. Secondly, the way in which the technology is situated within ANT due to the principles of generalized symmetry and agnosticism does not translate to understanding design needs from multiple perspectives [36]. Based on a preliminary analysis of principles, ANT does not provide an adequate basis for the development of a new needs-finding method for medical device development in LMIC.

2.2.1.2 Distributed Cognition

Hutchins and his colleagues developed the theory of Distributed Cognition in the mid-1980s. This theory posits that cognition is distributed among individuals, groups, and technological artefacts. This is contrary to traditional theories of cognition in which the focus is on the individual. Distributed Cognition defines a dynamic system that consist of artefacts, individuals and their relationship as the unit of analysis. Distributed cognition aims to analyze and interpret the relationships between the objects and individuals within a context, specifically looking at knowledge and cognition [37], [39], [40]. This theory has been used to study computer supported collaborative work (CSCW), human-computer interaction (HCI) and engineering practice. Distributed Cognition can be an informative approach to understanding how a specific system works when a new technology is introduced. By focusing on the cognitive behaviour of an individual within a specific context, the theory facilitates identification of miscommunications.

Using Distributed Cognition to understand the cognitive processes for how a medical device is used within a specific intervention can be beneficial for understanding the user interaction design needs. However, due to how technology is situated in Distributed Cognition Theory, it is challenging to understand design needs for producing and implementing a specific medical device within a larger socioeconomic context. In this thesis, the author is interested in developing a needs-finding technique that provides the basis for identifying design needs considering socioeconomic, clinical and technical factors. Distributed Cognition Theory is not an appropriate base framework for forming this technique.

2.2.1.3 Ethnomethodology

Phenomenology and ethnomethodology emerged from the work that Husserl did to understand how humans create a specific experience from an object. Schutz built on Husserl’s work and developed main principles in field of phenomenology that “posits that all objects exist because people perceive and construct them as such” [41]. Inspired in part by this early work, Garfinkel developed the basic principles of ethnomethodology, namely that "social reality and social facts are constructed, produced and organized through the mundane actions and circumstances of everyday life" [41]. Conversation analysis, interviews, and observations are common methods used within the study of ethnomethodology. Ethnomethodology, an interpretive method, focuses on the empirical study of social systems and, as highlighted in Section 2.1, its methods are frequently used for needs finding in human-centred and context-aware design for medical device development. Ethnomethodology tools can be used to provide a comprehensive account of a specific social system; however, lack of a theoretical framework for situating technology can lead to an insufficient understanding of the design needs [39].

2.2.1.4 Activity Theory

Activity Theory comes from a different background than the other three theories; however, it has also been used to understand the role of technology within society in various fields. Vygotsky, Leontiev, and Engestrom have made significant contributions to the inception and development of Activity Theory. In Activity Theory (AT), an activity is a unit of analysis and it is described through a framework, *an activity system.* The entire activity system involves a subject (main agent) and multiple community members; it accounts for the role of the artifacts, the motivation of the actor, division of labour and socioeconomic norms[39]. The most recent developments of Activity Theory provide two key principles that could be applied in design methodology. Firstly, AT allows for formation and analysis of a network of activity systems. Secondly, the theory defines *contradictions* as points of tension between various elements of one or multiple activity systems. Contradictions last until resolved through changes in activities [42].

Many scholars in fields of information systems [43], human-computer interaction [44], organizational behaviour [45], and education [46] have used principles of Activity Theory to guide their research. Based on the existing applications of AT and shortcomings of the other three theories, Activity Theory was chosen as the basis for the development of a novel needs-finding technique.

2.2.2 Motivation for using Activity Theory in medical device design

The author chooses Activity Theory as the basis for the development of a novel needs-finding technique for medical device development in LMIC because the theory offers two main advantages that address the existing shortcoming in needs-finding techniques. First, Activity Theory provides an explicit framework for situating technology with respect to a subject (i.e. a stakeholder), a motive, and its context. A triangular framework defines an activity system and forces designers to take a holistic approach for understanding an activity. Second, the Activity Theory introduces appropriate terminology for identifying and defining change within and between activity systems over some time, providing the basis for identifying desired change within a design space. The author builds on the existing framework and principles of Activity Theory to develop the Activity Theory-based Needs Finding (ATNF) technique. The next section provides a thorough background on Activity Theory and its application in relevant fields. Chapter 3 describes ATNF and illustrates its use through an example application.

2.2.3 Background - Activity Theory

The following three sections provide a brief history of Activity Theory, the most recent developments of the theory and a review of relevant application areas.

2.2.3.1 History of Activity Theory

Activity Theory (AT) has its foundation in cultural historical psychology and was developed by Vygotsky in the 1920s and 1930s [39]. This development in psychology was in response to the Russian Revolution and the quest for developing theories that align more with the Marxist political ideologies. Vygotsky defined a number of principles for cultural historical psychology. These principles were “unity of consciousness and activity” and “the social nature of human mind”. Vygotsky and many of the Russian psychologists believed that the human mind grows and evolves within the context of human interaction [39]. Therefore, they concluded that understanding human activities and interactions are critical for analysis of the mind. The other principle, “social nature of human mind”, states that the human mind is social in nature. This is derived from the philosophical standpoint of “social being determines consciousness”. The interaction between a person who is taking part in an activity is defined as “being”. These two principles led to a shift in types of psychological studies, which evolved to focus more on social activities rather than subjective or objective behaviours. Other psychologists including Gestalt and Piaget developed theories for understanding the broader social context [39]. However, cultural historical psychology had a more prominent focus on the role of culture in human development. Vygotsky also developed the idea of mediated action, which states that technology and artefacts act as mediators in human activities.

Leontiev, who was one of Vygotsky's students, provided two main contributions [47]. Firstly, he studied a historical development of the mind, from initial appearances of psyche in biological beings to the fully conscious human mind. Secondly, through his study of the mind, he developed the primary framework for AT, which provided the necessary tools to analyze the mind within an existing society and culture. Leontiev provided a basic description of activity: "I will call the processes of activity the specific processes through which a live, that is, active relation of the subject to reality is realized, as opposed to other types of processes" [48].
He also defined and introduced the concept of an *object* as the "true motive" of an activity and stated that an activity cannot exist without an object. An activity comes into existence when a subject has a need and has identified that need. The need becomes the motive or the object for the activity. In addition, Leontiev recognized that human mind development is influenced by cultural, political, technical and social parameters. Therefore, he studied tools, language and division of labour within the framework of an activity [39].

As the literature about AT was translated, more western psychologists further developed the theory, notably Engestrom [49], [50]. He drew upon the works of Vygotsky, Leontiev and Il'enkov to bring two new principles to AT. Firstly, he incorporated the idea that activities develop and change because of existing contradictions within or between two activities. Secondly, he brought up the idea that activities exist within networks, and this concept can be used for analysis.

2.2.3.2 Basic principles and framework of Activity Theory

The previous section introduced the primary principles of AT as developed through multiple generations. This section provides a more detailed description of the principles that are most significant for the development of the new needs-finding technique [39], [49], [51].

- **Activity as a unit of analysis:** An activity is the unit of analysis, according to AT. An activity is created from an interaction between a subject and an object within a certain context.
- **Object-orientedness:** All activities have an object. An object is the motive of the subject. An activity allows the subject to realize the motive.
- **Mediation:** The interaction between subject and object within an activity is mediated by language and artefacts.
- **Development:** Activity Theory initiated from studying development of the mind. Therefore, AT has an inherent emphasis on development over time. All components of an activity develop over time in correspondence to shifts within and external to an activity.
- **Contradictions for development:** Contradictions within and between various activities are points of tension. They are viewed as drivers of change and development.
- **A network of activities:** Activities can also be analyzed within a network along with other activities. The basic model of a network includes a minimum of two activities.

All these principles come together and support the framework of activity systems developed by Engestrom [52]. Figure 2-3 illustrates an activity system. Each activity system has 7 main elements: subject, object, outcome, instrument, community, rules and division of labour.

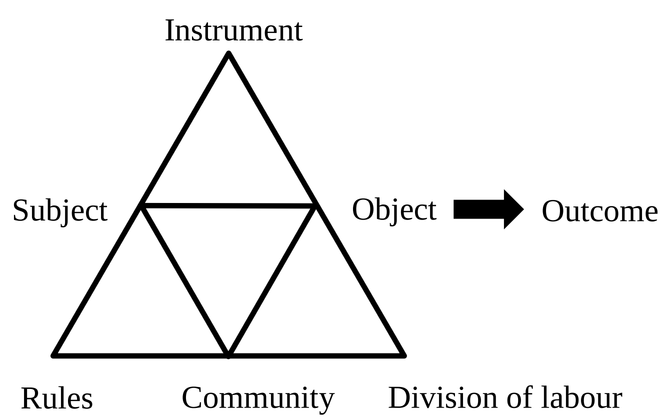


Figure 2-3 Activity System by Engestrom [52]

- **Subject** is an individual or a collective who is the primary agent for the activity.

- **Object** has been defined in a multitude of ways. There are primarily two main distinct definitions. The object can either be defined as the "problem space" or "raw material" that the activity is directed toward and this object is transformed into an outcome. Another definition, covered earlier in this chapter, is that object is the motive of the subject. The motive comes from needs of the subject.
- **Outcome** describes the transformed states due to the activity.
- **Instrument** is the physical artefacts and communication tools that the subject uses to reach the object.
- **Community** is the individual and collectives that help the subject reach the object.
- **Rules** are the social norms and rules that govern the specific activity.
- **Division of labour** refers to both the horizontal division of labour and the vertical division of power between community members.

Along with the framework for activity systems, Engestrom also developed a definition and classification of *contradictions*, which are the tension points that exist within or between elements of one or more activity systems [52]. There are four types of contradictions.

- **Primary**: the inner contradictions within elements of activity system
- **Secondary**: the contradiction between 2 or more elements of one activity system
- **Tertiary**: the contradiction between elements of an activity system and another activity system that is more "culturally advanced" due to time
- **Quaternary**: the contradiction between elements of two activity systems existing at the same time.

For examples of the application of the existing framework and further clarification, refer to [53]. These principles of Activity Theory and the frameworks for activity systems and contradictions form the basis for the development of a new needs-finding technique.

2.2.3.3 Review of Activity Theory applications in other fields

Activity Theory principles have been applied and used in many fields, including human-computer interaction (HCI), information and communication technologies (ICT), organizational behaviour and education. This section provides a brief overview of AT application in these fields.

The use of AT principles in HCI became more prominent on the international research scene in the early 1990s. Bodker's thesis was one of the first works that brought principles of AT into HCI design [44]. The main idea of her work was that a human-computer interaction needs to be viewed and analyzed within a wider context. Following Bodker's work, numerous other scholars started developing theories based on AT principles as a framework for HCI design and research [39]. One of the most relevant techniques was the Activity System checklist which has been used for design and evaluation of HCI technology [54]. The Checklist asks a series of questions about the role of HCI technology in four main areas: means and ends, social and physical aspects of an environment, learning and cognition and development [39], [54]. The Checklist informed the type of questions asked in the ATNF technique.

Activity theory principles have also been used in fields of information systems (IS) and information and community technologies (ICT). Kutti and other scholars used AT to study the implementation of IS [55]. For example, Wiredu used an activity system model to analyze the implementation of mobile technologies in healthcare development projects [56]. He used the framework to identify contradictions and record challenges with the implementation. More recently, Chen et al. used the AT framework to develop a data model for emergency fire hazard incidents [43]. The application of AT for assessment and design of IS system provides practical example of how the theory has been used to analyze a socio-technical system. These examples enhanced the author's understanding of AT and informed how an implementation of a medical device can be analyzed using AT. Similarly, AT has been used in studying the implementation and design of ICT. Kaptelinin et al. proposed five principles based on Activity Theory that could be used as a guiding framework for research on ICT for international development (ICT4D) [57]. The guiding framework for ICT4D allowed the author to choose the AT principles that are most relevant for development of ATNF (refer to Section 2.2.3.2).

Organizational behaviour and education are two of the fields that have used AT to develop further theoretical frameworks. Engestrom and colleagues have applied AT extensively into studying organizations and work settings, specifically healthcare systems [49]. This study illustrated the practicality of modelling healthcare systems using AT.

Activity Theory is used widely for analysing and designing educational environments and technology [58], [59]. Jonassen et al. developed a framework based on AT for designing constructivist learning environments [60]. The framework allows an educational designer to identify the needs and the desired outcomes for a specific educational setting. Activity Theory-based Needs Finding for medical device development in LMIC is informed by how Jonassen used Activity Systems to understand an educational setting.

Activity Theory has been applied to different degrees to design and evaluation of HCI, ICT, IS, organizational behaviour and education. The existing frameworks do not use AT as a basis for needs finding in medical device design and development for LMIC. These techniques also do not provide any *explicit* means of analyzing technical factors along with cultural, socioeconomic and clinical factors. However, all of the referenced studies have informed the development of a novel needs-finding technique for medical device development, specifically, the work done by Engestrom, Nardi, and Kaptelinin.

Chapter 3: Development of a Needs-Finding Technique Based on Activity Theory

3.1 Introduction

As outlined in Chapter 2, we posit that the existing needs-finding techniques for medical device development do not provide an effective framework for analyzing and connecting all aspects of this problem space within LMIC. A key contribution of this thesis is the development of a novel needs-finding technique based on Activity Theory that can be used by engineering design teams in their medical device development process. A well-crafted needs-finding technique can help a product development team develop the most appropriate needs and requirements that guide the rest of the design process – concept generation. This chapter provides a step-by-step description of the Activity Theory-based Need Finding (ATNF) technique and illustrates its application by performing ATNF analysis on a project called 3D-PrintAbility.

3.2 Overview of Activity Theory-based Needs Finding

The design process starts when the design team is aware of a problem. The ATNF has four main steps, as illustrated in Figure 3-1. The ATNF technique starts by identifying the main stakeholders and their activities within a problem space (refer to Section 3.2.1). The team needs to complete preliminary research and field observations before this first step. Then ATNF provides a framework for constructing an *activity system* (refer to Section 3.2.2). Once a design team constructs an activity system, they identify the *contradictions* (i.e., tension points) within or between various activities (refer to Section 3.2.3). Finally, each of these *contradictions* is translated into *need statements* with a specific desired change and metric (refer to Section 3.2.4). The following section describes each step in detail and highlights its features.

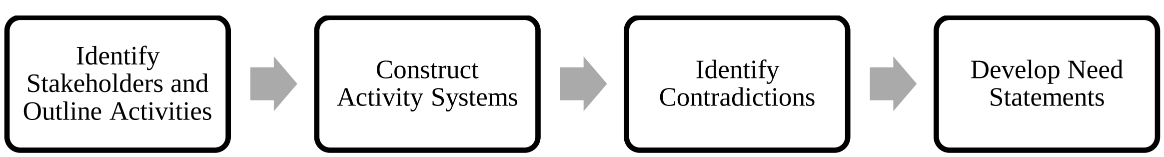


Figure 3-1 The Main Steps of the Activity Theory-based Needs Finding (ATNF) Technique

3.3 Step-by-step Description of the ATNF Technique

Each step within the ATNF has a specific role in the needs- finding process. Each step's key definitions and processes will be explained using as an example the case of an orthopaedic surgeon performing a femur fracture fixation in a low-resource environment.

3.3.1 Identify stakeholders and their activities

The first step of ATNF comes after preliminary research and observation of the problem space. The design team starts with the task of identifying the stakeholders. The stakeholders can be identified using various tools that are also used by other needs-finding techniques. For example, the Stanford Biodesign Process recommends Cycle of Care and Money Flow Analysis as a way of developing a list of initial stakeholders [14]. Human-centred design mainly suggests in-context immersion as a way of identifying stakeholders [23]. The ATNF uses a combination of these three to create a comprehensive list of stakeholders.

Once all the stakeholders are identified, the design team needs to define activities. ATNF uses the original definition of activity by Leontiev (Section 2.2.3.1). To identify an activity, it is necessary to define the subject and the object. The subject is an individual or an organization that is motivated and holds the agency to do an activity. Each stakeholder corresponds to a subject. All subjects have a number of objects. In the development of ATNF, the author chose to use the term "objective" instead of "object" to ensure clarity between the term and its definition. Building on Leontiev's definition of object (Section 2.2.3.1), an objective is the motive of the subject for doing the activity [39], [47], [48]. An objective is not a physical artifact, an individual or an organization. The objective is defined by answering the following questions: Why is the subject doing a certain activity? What are the motives of the subject? For instance, a nurse, an orthopaedic surgeon, and a sterilization unit are some of the key stakeholders for a femur fracture fixation surgery. Each one of these stakeholders is a subject with different objectives. The nurse wants to deliver high quality nursing care to the patient and as part of that, the nurse ensures that the surgeon has the necessary tools and provides assistance. An orthopaedic surgeon wants to perform high-quality surgery for the patient and for that performs the surgery according to standard protocols. Finally, a sterilization unit aims to deliver and maintain a standard level of sterilization.

Once the team develops a list of their activities by outlining the subjects (i.e., stakeholders) and their objectives (i.e., motives) they can move to the next steps of this technique, which is to construct activity systems.

3.3.2 Construct activity systems

In this stage, the design team needs to construct and define each element of the *activity systems*. The original template for an activity system developed by Engestrom is illustrated in Section 2.2.3.2. In developing ATNF, the author clarified definitions of constituents of the original *activity system* and added further key elements. The original definition of terms for *activity system* is broad for application in medical device design methodology, necessitating the development of more clear definitions for use by design teams. Hence, we devised a clearer terminology for its use as part of the ATNF technique. The ATNF *activity system* breaks down an *activity* into eleven major components: *subject* (i.e. stakeholder), *object* (i.e. motive), *community, physical instrument, non-physical instrument, technical rules, non-technical rules, division of labour* and *division of labour with respect to technology*. The modified *activity system* and corresponding prompt questions are illustrated in Figure 3-3. In addition, Table 3-1 contains the definitions of the elements of the modified activity system and corresponding examples. In addition to developing clearer terminology, the ATNF technique suggests a specific order of constructing activities so that the step-by-step process of constructing each activity is systematic and easy-to-follow for design teams.

It is important to note that both in the original AT and in ATNF, an activity system should be developed for each subject and objective. The design team can choose to define as many systems as they see necessary. For a more efficient and effective needs-finding process, the scope of an activity system should be specific and only include one activity. For example, “a hospital trying to provide quality care” as an activity system is large in scope for the problem of designing a new surgical tool and consists of many smaller activities. There are many activities involved with having a hospital deliver quality care – anywhere from surgery, the supply of instruments, to sterilization. There are many details and intricacies for each one of these activities; it would be useless to have all of this information in one activity system because it would be very challenging to decipher how everything is connected and what the problems in the system are.

Therefore, if an activity systems focuses solely on one specific activity, a more targeted analysis can be performed. For example, a nurse giving a certain piece of equipment to the surgeon during an orthopaedic surgery is of appropriate scope and can allow the design team to delve deeply into that activity. By ensuring that each system only focuses on one main activity, a design team can achieve a high level of granularity in their analysis of the situation. However, in order to achieve a highly-detailed analysis, a comprehensive list of stakeholders needs to be considered (refer to Section 3.2.1).

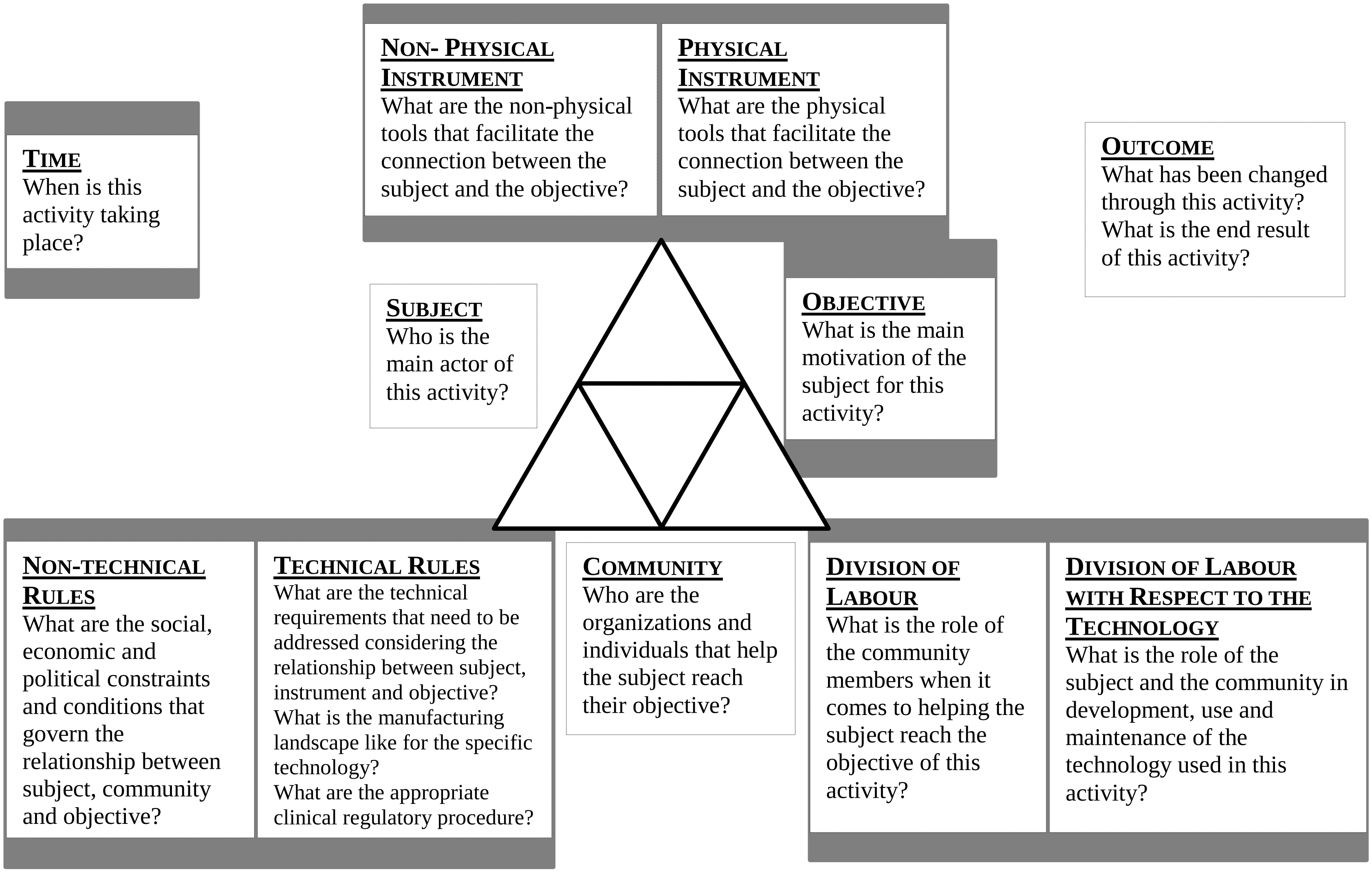


Figure 3-3 The Modified Activity System for ATNF – it includes the prompt questions that can be used by design team to develop the elements.

Table 3-1 The definition of terms and corresponding example of the ATNF modified activity system

Term	**Definition (correspond to questions in** Figure 3-3**)**	**Example**
Activity	Series of actions and interactions that a stakeholder can take within a context for a specific purpose	A femur fracture fixation surgery performed by an orthopaedic surgeon in Uganda
Subject	A stakeholder who has the agency to participate in an activity to reach the objective	Orthopaedic surgeon
Objective	The motive of the stakeholder for engaging in the activity	To provide care to the patient
Time	The timeframe during which the activity is taking place	During the surgery
Outcome	The resulting changes after the activity	Femur of the patient is properly fixed
Community	All stakeholders who help the subject reach the objective at that time	Nurse Sterilization staff Hospital admin
Physical instrument	All the tools and technology that the subject uses to accomplish the objective	Surgical drill, screws, plates, dressing, sutures, tourniquet
Non-physical instrument	The language, knowledge, and protocols that the subject uses to accomplish the objective	Surgical experience Specific protocols in the operating room
Technical rules	All the constraints, conditions and regulations necessary for the optimal function of the physical instrument	The surgical drills need to be powered. The surgical drill needs to be sterilizable.
Non-technical rules	All the social norms, economic constrains and political system rules that influence the activity directly	Nurses often follow the orders of the physician The hospital admin provides a limited amount of equipment based on limited financial resources
Division of labour with respect to technology	The role of the subject and community members with respect to the physical instruments	Scrub nurse prepares the drill for the surgeon The sterilization team needs to sterilize the drill
Division of labour	The role of the subject and community members in helping the subject reach the objective	Nurse ensures the surgeon is scrubbed in The hospital admin allocates money and resources for the operating room

3.3.2.1 Step 1 - Outcome, time and community

After defining an activity by identifying the subject and the objective, the design team constructs an activity system by first describing outcome, time and community, in order. This order of construction is not outlined in the original theory; however, since it is much easier for a design team to work through understanding an activity when given a specific workflow, it is important to have an order. Table 3-1 illustrates the refinement to the definition of the basic elements. Figure 3-3 highlights the modified elements of the activity system.

Outcomes are well-defined and quantifiable changes that are expected to result from the activity. For example, the outcome of a femur fracture surgery is that the fracture is fixed in a standard way. Time is explicitly included in the modified activity system because it enables the design team to be more aware of the timeframe that this activity is taking place and to choose the specific rules and division of labour accordingly. For example, for the femur fracture fixation case, the relevant activities are different before, during and after the surgery. Once the time, subject, objective and outcome of an activity are determined, the design team can determine the community. Community for an activity consists of all the stakeholders that help the subject reach the objective. In the case of a femur fixation, nurses, sterilization unit and medical device suppliers form the community for that activity. Once time, subject, objective, outcome and community are defined for an activity, the basic context of the activity is set. The next three elements further define and specify the activity.

3.3.2.2 Step 2 - Instruments, rules and division of labour

Unlike the original AT, in ATNF, instrument, rules and division of labour are all divided into two distinct categories. The instrument is divided into physical and non-physical. Physical instruments are tangible tools that a subject uses to reach the objective. For example, an orthopaedic surgeon uses various tools such as a surgical drill to perform a femur fracture fixation. On the other hand, non-physical tools refer to specific protocols, language, and knowledge that is used by subject to reach the objective. For example, an orthopaedic surgeon uses experience, specific language, and surgical protocols to perform a standard surgery. Rules are divided into two sections – technical rules and non-technical rules. Technical rules refer to constraints and conditions imposed by the physical instruments. For example, a surgical drill needs to be designed to ensure a certain level of safety and accuracy. Non-technical rules refer to laws, economic constraints and social norms that are in place for that activity. For instance, a hospital has a limited budget to pay for instruments and staff time. Finally, the division of labour is divided into two sections: division of labour with respect to technology and the generic division of labour. The division of labour with respect to technology specifically focuses on how different stakeholders are involved in creating, funding, regulating or using the physical instruments. A scrub nurse is often the one who is setting up and handing the instruments to the surgeon. The generic division of labour refers to how else the tasks are divided and completed by different community members. For instance, a nurse often performs the protocol for closing the wound, documenting and cleaning the OR.

3.3.3 Identify contradictions

At this point, the design team should have a comprehensive understanding of their problem space once they have constructed the activity systems. In this step, the team needs to identify *contradictions*. This research uses the definition of *contradiction* developed by Engestrom, in other words, contradictions are points of conflict or tension within or between elements of one or multiple activity systems [49], [52]. Engestrom states that contradictions cannot exist for a long time within or between activities because they disrupt the system of activities [49], [52]. These contradictions (i.e., problems) need to be addressed. Some of these contradictions are mainly technology-based; however, they often cover a wide range of issues. For example, electricity supply is often unreliable within a low-resource operating room and on the other hand, most of the donated equipment in the operating room is wall powered. There is a contradiction between the environmental constraints (i.e., technical rules) and the existing physical instruments. Engestrom identified four main types of contradiction within a network of activity systems, defined in Section 2.2.3.2. In ATNF, these four types are used to provide some guidance and direction for a design team as they identify contradictions. The design team can first identify primary and secondary contradictions within an activity and then proceed to identify tertiary and quaternary contradictions between activities. In this way, more granular contradictions are identified first and then more system-level contradictions follow.

By identifying contradictions between and within activities, the design team can start understanding the needs of their stakeholders. The next section describes how a design team can develop need statements from contradictions.

3.3.4 Develop need statements

As highlighted in the previous section, contradictions need to be addressed over time. Each contradiction indicates a problem within the activity system that can be translated into a *need statement*. The Biodesign process explained in Chapter 2 informed the ATNF definition and development of *need statements*. According to the Biodesign process, a *need statement* needs to express a *desired change*, *target audience* and a *metric* [61]. A *need statement* should also have a specific scope and choices of words [61]. A design team can develop a need statement by mapping a contradiction to the desired change and by deriving a metric based on the outcome of the activity systems. The design team can then refer to the activity systems and the contradictions to choose the specific scope and words for the need statement. For example, "To develop surgical instruments that use available power sources in low-resource hospitals" is a need statement that corresponds to the contradiction identified in the last section. A need statement can either correspond to one or multiple contradictions. The author recommends that a design team can go through these last two steps iteratively until they develop a specific set of need statements and metrics that identify and characterize the desired changes.

The ATNF technique can be taken further and the design team can use the information from each element of an activity system to develop more specific functional requirements. However, this last step is not thoroughly evaluated and is beyond the scope of this thesis.

3.4 Sample Application to a Case Study

To demonstrate the use of the proposed needs-finding technique in a real-world problem space, ATNF was applied to the 3D-PrintAbility Project. The following includes a background description of the project and an example of how ATNF can be used to identify needs within the medical device design space in less-industrialized economies.

3.4.1 Background

The 3D-PrintAbility Project is a collaboration between the University of Toronto, Christian Blind Mission and CoRSU Rehabilitation Centre, an institution in Uganda. The team developed a 3D scanning and printing system for fabricating low-cost, fully customized, below-knee prostheses. The author investigated the 3D-PrintAbility project via online resources and also by participating in a tour of the CoRSU facility near Entebbe [62]–[64]. For the purposes of this case study, the author analyzed CoRSU's prosthetics manufacturing process *before* the 3D-PrintAbility project was initiated. The main purpose of this case study was to identify the needs of CoRSU's original prosthetics manufacturing process using the ATNF technique. The common practice of CoRSU's orthopaedic technologist was to use traditional plaster-casting methods to fabricate prostheses [65]. The plaster-casting method is a standard practice approved by the International Society for Prosthetics and Orthotics (ISPO) for fabricating prostheses. The following four sections provide a detailed description of each step of ATNF as applied to the 3D-PrintAbility project.

3.4.2 Identify stakeholder and their activities

The author chose to perform Cycle of Care and Flow of Money Analysis on the 3D-PrintAbility project. Figure 3-4 and Figure 3-5 provide an overview of these two methods.

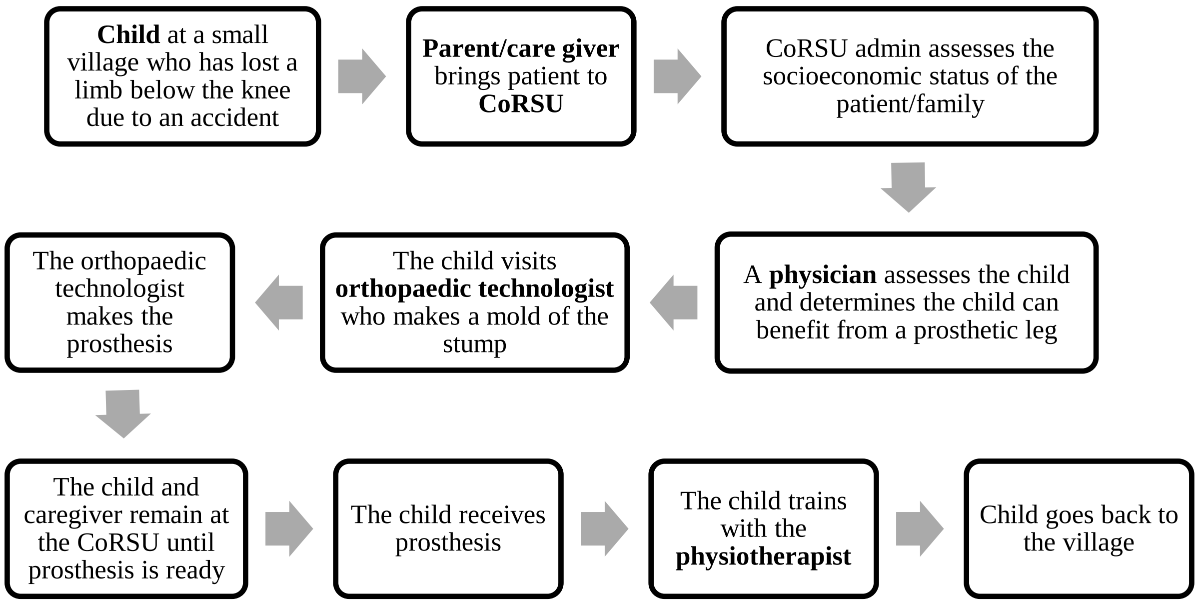


Figure 3-4 Cycle of Care Analysis for Prosthetic Services at CoRSU

Figure 3-5 Money Flow Analysis for Prosthetic Services at CoRSU

The following stakeholders were identified from a preliminary Cycle of Care and Flow of Money Analysis: patient (i.e., child), orthopaedic technologist, caregiver physician, physiotherapist, CoRSU, Christian Blind Mission (CBM), and supplier.

The following is the list of activities for each of the stakeholders:

- Activity 1– patient wants to be able to do daily tasks such as walking while at CoRSU

- Activity 2 – patient wants to be able to do daily tasks such as walking after leaving CoRSU
- Activity 3 – orthopaedic technologist provides care for patients
- Activity 4 – orthopaedic technologist needs to earn a living
- Activity 5 – physician provides care for the patient
- Activity 6 – physiotherapist ensures that the patient can do the necessary functional tasks with the new prosthesis
- Activity 7 – CoRSU buys the necessary supplies
- Activity 8 – Supplier sells their products and obtains profit

The exercise of identifying activities does not have a well-defined limit. A design team should identify activities until they have a thorough understanding of the entire system. In this case, the above eight activities provided a good starting point. More activities can be added and analyzed later in the process if necessary. It is important to note that some subjects such as the 'patient' and 'orthopaedic technologist' have two activities with different objectives and times. Analyzing eight activities at the same time can be highly complex; therefore, for the next step, the research team chose to start investigating three specific activities.

3.4.3 Construct activity systems

The next step is to construct activity systems using the template in Figure 3-3. For the purpose of this case study, we focused on three activities: "orthopaedic technologist – to provide the best possible care to the patient", "patient – to be able to do daily activities independently while at CoRSU", "child – to be able to do daily activities independently after leaving CoRSU". The three activity systems are illustrated in Figure 3-6, Figure 3-7 and Figure 3-8, respectively.

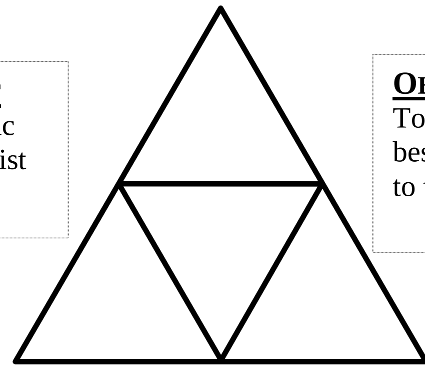
TIME
When the child is at CoRSU

NON- PHYSICAL INSTRUMENT
Orthopaedic technician's professional training and knowledge of development of prosthetics

PHYSICAL INSTRUMENT
The machinery and tools for making below-knee prosthesis

OUTCOME
The patient receives a prosthetic leg and can start training to walk

SUBJECT
Orthopedic technologist



OBJECTIVE
To provide the best possible care to their patients

NON-TECHNICAL RULES
1. The most time consuming part of the making of a prosthetic is creating the right shape for the patient.
2. There are only a limited number of trained orthopaedic technologists
3. Cost breakdown of the material and labour

TECHNICAL RULES
1. The procedure for making the prosthetic
2. The standards that orthopaedic technician needs to follow according to ISPO
3. Certain tools require a source of electricity

COMMUNITY
Caregiver
Patient (i.e. child)
CoRSU admin
Physiotherapist
Supplier

DIVISION OF LABOUR
1. Caregiver takes care of the on-site needs of the patient
2. CoRSU admin pays for the orthopaedic technologist's time
3. Suppliers provide the necessary equipment and necessary maintenance

DIVISION OF LABOUR WITH RESPECT TO THE TECHNOLOGY
1. The caregiver receives appropriate instruction on how to take care of the prosthetic.
2. The orthopaedic technologist makes and modifies the prosthetic until the fit is appropriate.
3. The orthopaedic technologist trains the patient to use the prosthetic.

Figure 3-6 Orthopaedic technologist providing quality care activity system

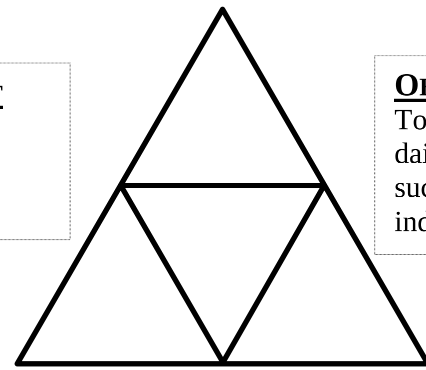
TIME
When the child is at CoRSU

NON- PHYSICAL INSTRUMENT
Training for use of the prosthetic leg

PHYSICAL INSTRUMENT
Prosthetic leg

OUTCOME
The patient receives a prosthetic leg and is trained to walk.

SUBJECT
Patient



OBJECTIVE
To be able to do daily activities such as walking independently

NON-TECHNICAL RULES

1. The patient and caregiver need to travel for few hours to reach CoRSU.
2. The price for below the knee prosthetic is $150-200
3. CoRSU has limited budget for prosthetics.
4. The patient and caregiver often need to stay at CoRSU while they are waiting for the prosthetic.
5. The patient receives free prosthetic care depending on socioeconomic status

TECHNICAL RULES

1. It takes one week to create a full prosthetic leg.
2. The fit of the prosthetic leg should be custom for the patient and should not cause any discomfort in the long run.

COMMUNITY
Orthopaedic technologist
CoRSU administration
Physician
Physiotherapist
Nurse
Caregiver

DIVISION OF LABOUR

1. Caregiver provides basic care for the patient.
2. CoRSU admin assess patient's socioeconomic status.
3. The caregiver is often the breadwinner in the family and provides for the patient.

DIVISION OF LABOUR WITH RESPECT TO THE TECHNOLOGY

1. The caregiver is trained to help the patient with using and maintaining the prosthetic limb.
2. The CoRSU admin need to ensure that proper resources are available.
3. Orthopaedic technologist makes the prosthetic and trains the patient.

Figure 3-7 Patient at CoRSU activity system

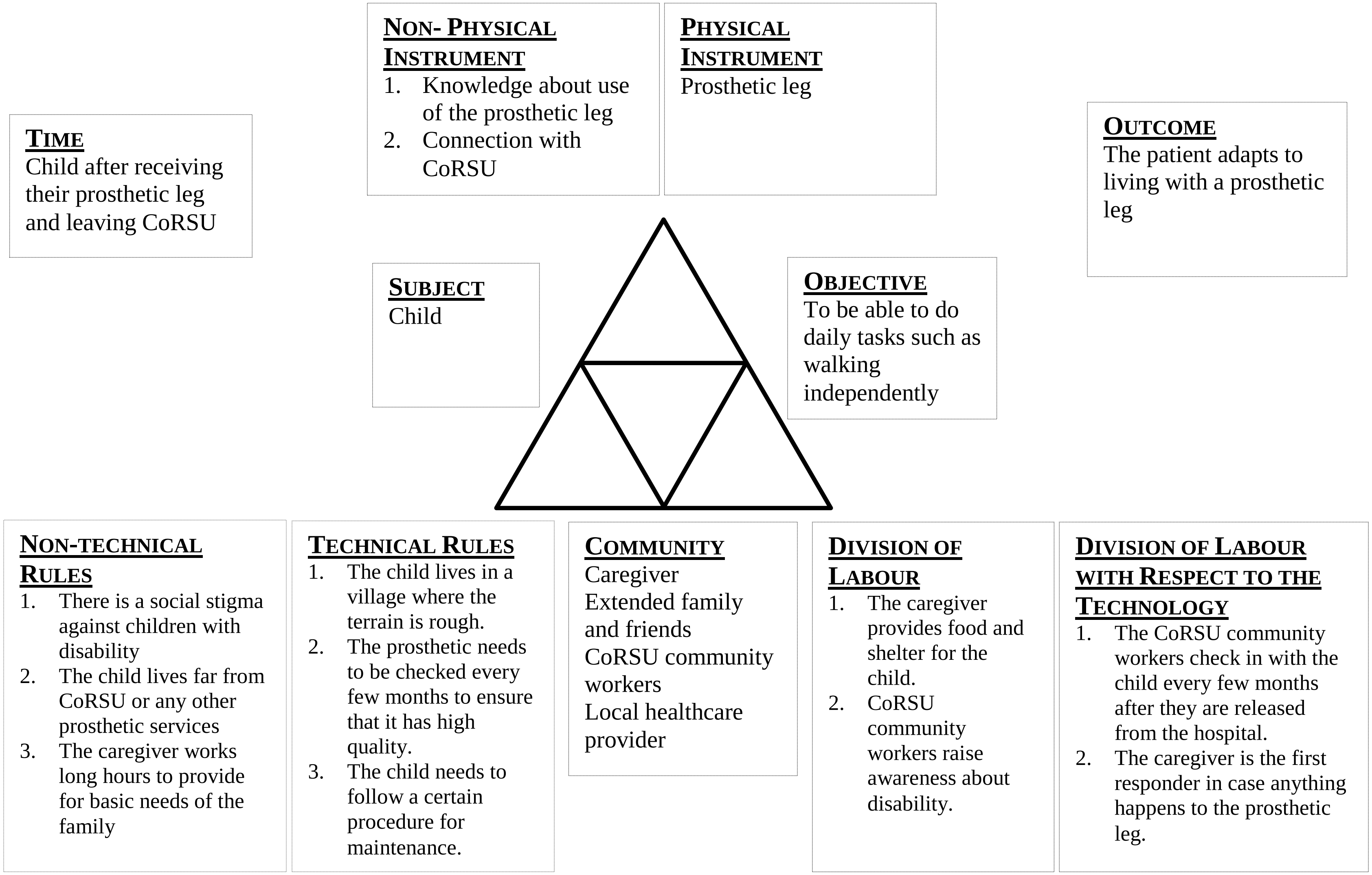


Figure 3-8 Child after leaving CoRSU activity system

3.4.4 Identify contradictions

The following contradictions were identified between the three activities:

Primary contradiction between the rules in the patient activity (while at CoRSU):

1. CoRSU's budget is limited in its ability to provide prosthetics services. Even with the low cost of $150-$200 per prosthetic leg, with the available funding they cannot afford to provide solutions to all children who need them. To maximize the number of children served, they conduct a socioeconomic assessment of their patients and offer free services only for patients who cannot afford to pay for their own prosthetics. The contradiction lies in the fact that patients want to be able to perform daily activities, and CoRSU has a financially driven rule, which is that they cannot provide free service to everyone in need. This tension between a patient's wants and CoRSU's inability to deliver the wants is categorized as a contradiction.

Secondary contradiction between technical rules and non-technical rules for child (after leaving CoRSU):

2. The prosthetic limb needs to be checked and maintained over time. The child often lives far from CoRSU. The contradiction is between the technical rule for maintaining the device and the environmental constraint of where the child is living.

Quaternary contradictions between activities of orthopaedic technologist and patient at CoRSU:

3. Caregivers are often the breadwinners in the family and therefore work to provide for their children (the patients). However, caregivers have to be at the hospital, often far from their hometown and must stop working for approximately two weeks while the patient is being fitted with the prosthesis. This situation creates an extra financial burden on the caregiver and patient. The contradiction lies between financial rule within the child activity at CoRSU and the amount of time it takes to actually make a prosthetic limb within the orthopaedic technologist activity.

4. The prosthesis fit should be such that the patient is comfortable when wearing it daily for a period of 2-3 years. However, the prostheses are made by hand, resulting in a high incidence of human error involved in their fabrication. The contradiction is between the activity of patient after leaving CoRSU and the orthopaedic technologist activity of making the prosthetic device

at CoRSU. How the device needs to be used by the child is in contradiction with the inadequacies of the manufacturing method for the device.

3.4.5 Develop need statements

As highlighted, the contradictions were translated into need statements by identifying the *desired change*, *target audience* and *metric*. The need statements that correspond to the above contradictions are:

- A method to provide affordable and quality prosthetics to patients with a challenged socio-economic status. (from contradiction 1)
- A method to provide more accessible prosthetics services to patients living in remote areas. (from contradictions 2 and 3)
- A method to develop prosthetics with a more accurate and a customized fit for patients such that the prosthesis can be used for a longer period of time. (from contradiction 4)

It is important to note that a need statement does not express a solution. In addition, a need statement can also include two or more contradictions, as seen above.

3.5 Discussion and Summary

The ATNF technique is a four-step process based on principles of Activity Theory. Constructing activity systems and identifying contradictions are two of the distinguishing steps of this technique. These two steps allow the design team to go from identifying the stakeholders to developing need statements. In this chapter, the application of ATNF is demonstrated for the 3D-PrintAbility project. The four-step ATNF process and the modified activity system model were used to map out three main activity systems for this project. The contradictions from these three systems helped to outline some need statements. The technique was successfully used to identify socioeconomic, technical and clinical contradictions within the need statements.

Chapter 4: Comparative Study of Biodesign Needs-finding Technique versus the ATNF Technique

Chapter 2 discusses the existing needs finding tools for medical device development. Chapter 3 details the Activity Theory-based Needs Finding (ATNF) method. This chapter outlines the comparative study, designed to empirically compare the application of the ATNF method versus a conventional method, the Stanford Biodesign process. The chapter discusses the data collection and analysis methods used to study how engineering student design teams used a conventional needs-finding technique versus the ATNF technique. The chapter begins with a description of the study objective (Section 4.1) and design (Section 4.2). The data collection and analysis methodology are outlined in Sections 4.3 and 4.4, respectively. The results and discussion from this study are highlighted in Chapter 5.

4.1 Study Objective

Needs-finding techniques used in engineering design have improved over the years as explained in Chapter 2. The objective of this study was to compare the outcome and the process of the ATNF technique with a conventional needs-finding technique. Such a comparative study will allow the researcher to identify areas of improvement offered by the ATNF technique. The author chose to use the needs-finding technique used in the Stanford Biodesign process as the conventional method. This method provides an appropriate comparison for the ATNF technique because the Stanford Process includes principles of design for context [30], and it has been used numerous times for medical device development in both HIC and LMIC [66]–[68], indicating its versatility and adaptability.

The two needs-finding techniques are compared on the basis of the process and outcome. The study has two main goals. First, in order to assert the efficacy of ATNF as a useful needs-finding technique in medical device design, it is important to understand how design teams adopt, apply, and use ATNF in their design practice. Can design teams apply the ATNF technique to develop need statements? If so, what do the design teams think about the process of developing these need statements? Second, to understand the quality of the ATNF technique, it is critical to study how the ATNF technique performs versus a prominent conventional technique such as the Stanford Biodesign process. According to the Biodesign process, a need statement has to capture an appropriate scope, correct desired change and specific metric using context-specific words. Which method allows the design teams to capture a more comprehensive scope, appropriate metric, suitable words and accurate desired change for their need statements? Does one technique allow a design team to cover a broader spectrum of socioeconomic, clinical and technical issues? These are the questions that the study aims to answer. The hypothesis is that the design teams will be able to successfully apply the ATNF technique to develop need statements. It is expected that the ATNF technique will be more effective in guiding the teams to consider and integrate socioeconomic, clinical, and technical issues in their development of the need statement.

4.1.1 Research Ethics and Study Participants

Students from the UBC Engineers-in-Scrubs (EiS) biomedical engineering graduate training program and the Biomedical Engineering Student Team (BEST) were invited to participate in the study. All the EiS students were pursuing a graduate degree in biomedical engineering and had some previous experience in engineering design, but not necessarily in medical device design. All of the EiS projects were at the needs-finding stage of the design process. The EiS teams were following along the Stanford Biodesign Process as part of their graduate course [69] and were assigned within the course based on student interest in a project area. There were in total three teams within the 2015-16 cohort, consisting of a total of 15 students enrolled in the EiS program. From this cohort, 12 students, split between three groups, agreed to participate in this study. The BEST team is an extra-curricular undergraduate engineering student design team with about 80 members. The study invitation was sent out to all of the BEST members, and 18 students agreed to participate in the study. These eighteen participants were divided into groups based on their availability, design experience level and their team project. The BEST study teams consisted of undergraduate students in engineering and their background in medical device development varied between junior and senior participants. All of the participants were working on a project related to biomedical engineering, and these projects were all at different stages in the design process.

In total seven teams, three EiS teams and four BEST teams, participated in the study. There were a total of 30 participants between the two groups. A minimum number of three people and maximum number of five people formed the teams. All the participants provided informed consent as approved by Behavioural Research Ethics Board of British Columbia, as provided in Appendix B

4.1.2 Two Needs-Finding Techniques: ATNF and Biodesign

The teams were facilitated through two needs-finding techniques: the ATNF technique and the Biodesign process. The ATNF technique is described in Chapter 3. Figure 3-1 provides an overview of the four main ATNF steps, which are as follows:

- identifying stakeholders and their activities;
- constructing activity systems;
- identifying contradictions; and
- developing need statements.

The Biodesign Process is a recent medical device development process developed through the Biodesign innovation training program at Stanford University. Zenios, Makower and Yock leveraged the experience and insights of many engineers, physicians, entrepreneurs and design practitioners to develop their formulation [61]. The process is divided into three main stages: identify, invent and implement. Figure 4-1 shows the suggested needs-finding method as part of the “identify” stage in the Biodesign process. Table 4-1 provides the description of terms used in the Biodesign process.

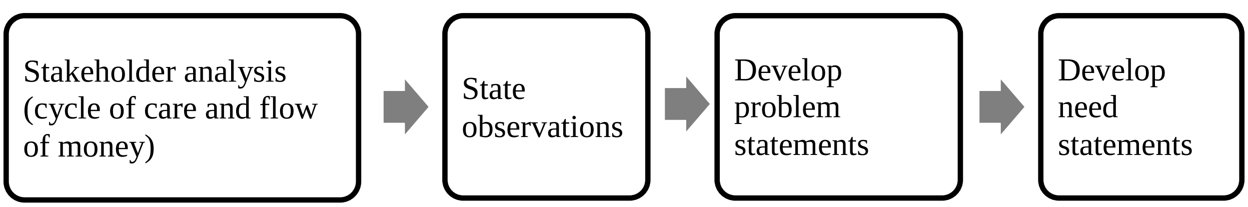


Figure 4-1 The needs-finding technique in the Stanford Biodesign Process

Table 4-1 Definition of Terms for Biodesign Needs-finding Technique

Cycle of care	The entire process of how care is delivered to the patient
Flow of money	A representation of sources, receivers and distribution of money
Observations	The data and information from field research
Problem statement	A statement highlighting the inadequacies or limitations derived from observations
Need statement	A statement that identifies a necessary change and includes a metric

The Biodesign process is a need-driven design method and emphasizes that medical device development should correspond to a real need [14]. Prior to needs finding, the design teams are required to learn as much as they can about their specific problem space [14]. The needs finding in Biodesign starts with a stakeholder analysis by outlining the cycle of care and flow of money. These two frameworks allow the design team to identify the major stakeholders and understand their roles. Once the major stakeholders are identified, the design team is asked to note all the observations that they have made through their investigations. Once sufficient observations are made, the design team synthesizes the information and develops problem statements. This technique emphasizes the importance of understanding the problems of the various stakeholders and transforming them into needs. Finally, the design teams develop a need statement corresponding to one or multiple problem statements [14].

4.1.3 Needs Finding Design Workshop

The design teams were asked to participate in a 2-hour workshop, facilitated by the author of this thesis. Each team came into the workshop with two design problems that they had researched previously. Each team started with applying one of the needs-finding techniques on one of their design projects. To avoid bias, the Biodesign needs-finding technique was referred to as *method A* and the ATNF technique was referred to as *method B*. The order of the techniques was randomly selected by the facilitator. From seven workshops, three of them started with method A and the others with method B. Each team chose the order of the design problems. The workshop started with a brief 10-minute introduction of the research project, completion of the consent forms and overview of the workshop agenda. Following that the teams were introduced and facilitated through either one of the methods step-by-step. The facilitator tried to ensure that approximately 45 minutes was dedicated toward each technique. However, it took from 30 minutes to 1 hour for each team to complete each technique. The teams were asked to record all of their work on flipchart papers, white boards or post-it notes. The sessions were also video recorded. After completing the two needs-finding exercises, each participant was asked to complete a post-workshop questionnaire. Detailed facilitation guidelines and the post-workshop questionnaire are included in Appendix B

Figure 4-2 Pictures from Workshops for Two Focus Groups

4.2 Data Collection Methodology

The author conducted an ethnographic study of the teams during the workshop and collected data from two sources to capture the design process and its outcomes. The design artefacts, and the post-workshop questionnaires were the two sources of data. All the sessions were recorded using two cameras; however, the video footage was not used for any form of analysis. This was because of the quality of the videos was not adequate, and the required information about the process of using each of the techniques and the result of the group discussion were captured through the other two forms of data.

4.2.1 Design artefacts

During the workshop the teams were asked to write their ideas throughout all the stages of needs finding on flipchart paper, post-it notes and whiteboard. Figure 4-3 and Figure 4-4 illustrate a few of these design artefacts. Each of the seven teams had a set of design artefacts for each of the two needs-finding techniques, totalling 14 sets of design artefacts. The design artefacts captured the details that each team developed for each stage of the needs-finding techniques for every one of the design problems. All of the design artefacts are transcribed and presented in Appendix A **Error! eference source not found.**

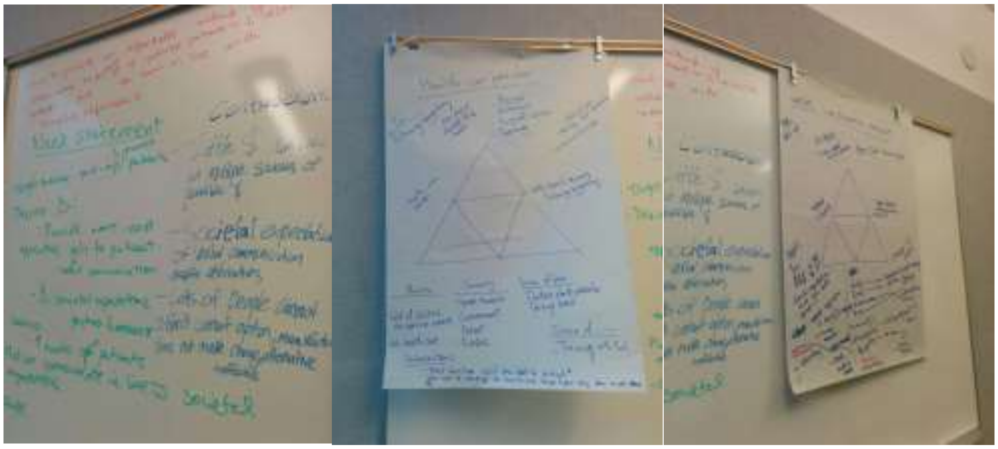


Figure 4-3 Part of Design Artefacts from FG1 Application of ATNF

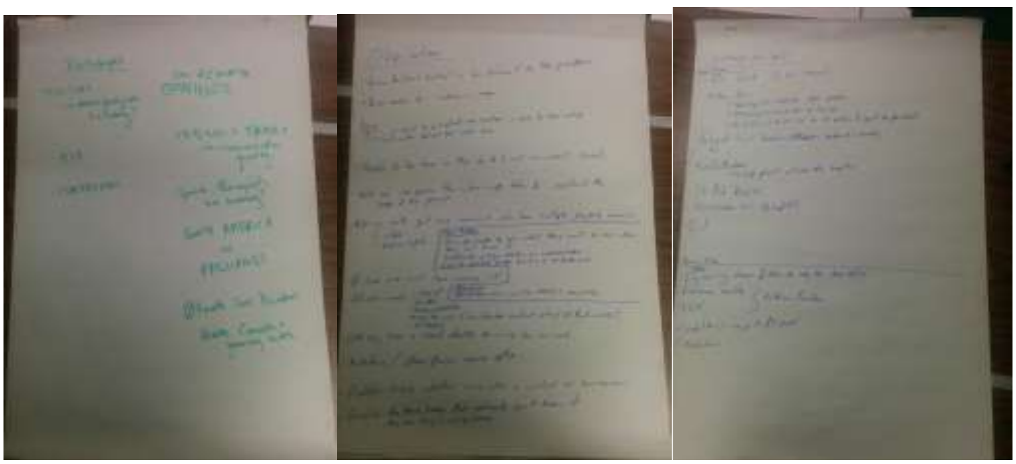


Figure 4-4 Part of Design Artefacts from FG1 Application of the Biodesign Technique

4.2.2 Questionnaires

Each of the participants completed a questionnaire comparing and expressing their opinion on each one of the needs-finding techniques and its impact on the quality of need statements that were developed. The participants also provided feedback about their overall experience in the workshop. The questions were all open-ended. There is a lack of literature on techniques that could be used to assess the quality of a need statement. Therefore, the questions were designed to allow the participants to openly reflect on the two techniques based on the four main elements of a good needs statement as identified in the Biodesign process. The four elements were the scope, the metric, the words, and the desired change expressed in the need statements [14]. The participants were asked to identify and compare the two techniques in answering the following five questions:

1. How did you use each one of the tools to identify the appropriate scope for your need statement?

2. How did you use each one of the tools to come up with context-specific words for your need statement?
3. How well did each one of the tools help you define an appropriate metric?
4. How well did each one of the tools help you define a desired change for your need statement?
5. Do you have any other comments about the two needs-finding techniques? Please elaborate.

All of the participants filled out the post-workshop questionnaire, and there were in total 30 responses. The full questionnaire is included in Appendix B.4.

4.2.3 Overview of the projects

The following table contains a list of the projects and need statements that were developed by each team. Focus groups 1, 3 and 4 started the workshop with the Biodesign technique. The remaining groups (2, 5, 6 and 7) started the workshop with the ATNF technique. Each team had come in with two projects for needs finding analysis in the workshop. They had conducted preliminary field and secondary research for both of the projects prior to attending the workshop. The transcribed contents of the design artefacts are included in Appendix A

Table 4-2 List of Projects and Need Statements (FG - Focus Group, AT- Activity Theory-based Needs Finding, BD - Biodesign)

Identifier	Need statement
FG1-AT	Need to provide an affordable method of verbal communication to increase the number of post-op patients in low resource settings that can communicate in line with societal expectations
FG1-BD	A method for obtaining eye movement data during vertigo attack for a physician, which can be obtained reliably and remotely, from the hospital, affordably, & easy to use
FG2-AT	A method of occluding blood that reduces the number of patients who are injured by improperly tightened tourniquets in low resource hospitals
FG2-BD	A method to reduce the number of delays caused by power outages, and maintain illumination during outages and surges for endoscopes
FG3-AT	A method to reliably cut and cauterize tissues even of the event of power outages to reduce blood loss during the operation

FG3-BD	A system to reliably see inside the urinary tract to increase the number of diagnosis of urinary diseases for female patients in low resource setting
FG4-AT	A method to increase the efficiency of the donation system by more effectively matching donors with recipients through distributors, and by increasing the percentage of successful and high-quality donations
FG4-BD	A method to improve traction treatment in low-resource system to reduce hospital stay time and better bone union in a larger percentage of patients
FG5-AT	A low cost method to ensure and expedite occurrence of respiratory rate monitoring and improve respiratory distress detection for pediatric patients with respiratory conditions in low resource settings
FG5-BD	A method to improve jaundice treatment process for newborn babies in low resource settings by ensuring proper treatment duration and minimizing adverse effects
FG6-AT	A method to increase efficiency in trauma units so that they can provide improved patient care in Kenyan hospitals as indicated by satisfaction of doctors and nurses and overall cost of implementation
FG6-BD	A method to improve emotional response to physical therapy for stroke patients facilitated by musical therapist so that patients adhere to their prescribed therapy
FG7-AT	A method to improve the treatment of jaundice by using minimal resources (costs, staff, time) for hospital staff in low resource countries so that treatment time is reduced
FG7-BD	A method to continuously monitor respiratory rate in children for hospital staff (nurses) in Ugandan hospital so that they can take action when necessary, which will reduce time observing patients and allow more time to treat patients

4.3 Data Analysis Methodology

The questionnaire responses and design artefacts were the two main sets of data analyzed. The following sections provide a description of the analysis methods for each of the data sets.

4.3.1 Mapping Need Statement Analysis

The objective of this analysis was to investigate the relationship between the words that each team chose to use in the first three stages of each needs-finding technique and the words that they used for the need statement. For each set of design artefacts, the words from the need statement were mapped to the words in the design artefact. The aim was to understand how the words in the need statements emerged from the needs-finding process and to see if there were any significant differences between the two techniques. In addition, the analysis investigated which stage of each needs-finding technique was more directly correlated with the need statements considering the use of words. The number of need statement words that appear in the first three stages of each techniques, the total number of appearances of need statement words in the design artefacts and the total number of appearances of need statements words in each stage of each technique were the three main variables that were considered in this analysis. The first two variables indicate how closely the words in the need statements were tied to the words that were used in the first three stages. The third variable indicates the correlation between the need statement words and the words used in each stage of each technique. As needed, these variables were normalized based on the number of words in the need statements and the design artefacts. The values from the ATNF technique and the Biodesign needs-finding technique were compared.

4.3.2 Category-based Content Analysis

Content analysis is a common method of analyzing written text, and it allows the researcher to systematically categorize the data in a replicable way [70]. Content analysis can be done quantitatively and qualitatively. Thematic analysis (Section 4.3.4) is a type of qualitative content analysis [71]. Quantitative analysis techniques provide the means of enumerating characteristics of content such as text or video [72]. The most common form of content analysis for written text is word frequency analysis. Category-based content analysis on the design artefacts examines the words themselves and divides them into various categories based on “meaning or connotation”

[73]. The categories need to be mutually exclusive, in other words, a phrase that is put into category A cannot be put into category B. In addition, the list of categories needs to be fully exhaustive and cover all the possible topics for the content [73].

The objectives of this analysis were to understand the range of issues that each set of design artefacts covers and to examine the differences between the two sets based on the needs-finding techniques used. The author chose to categorize the design artefact into seven categories based on the PESTLE analysis, a technique recommended in the USAID Idea-to-Impact toolkit for development of medical devices for low-resource environments [10], [74]. The PESTLE technique prompts the designer to look at “Political”, “Environmental”, “Social”, “Technical”, “Legal” and “Economic” factors pertaining to a specific problem space. For this analysis, the author added “Clinical” as the 7th category, considering the nature of the design problems. The author hypothesized that the design artefacts from the application of the ATNF technique would have a higher percentage coverage of the political, environment, social and legal categories. The author expected that there would be no difference for percentage coverage of the economic, clinical and technical categories since the Biodesign needs-finding technique explicitly focuses on those factors. All of the design artefacts were coded into these seven categories by two researchers to ensure the reliability of the analysis [75], [76]. The two sets of design artefacts from each of the needs-finding techniques were compared based on the percentage coverage of each category.

4.3.3 Sentiment Analysis

Sentiment analysis, or opinion mining, uses computational techniques to identify positive and negative sentiment of an assertion [77], [78]. Sentiment analysis was conducted on the questionnaire responses to investigate the opinion of the participants for each needs-finding technique. The field of sentiment analysis is evolving quickly and there are currently variety of techniques and tools available. Rebeiro et al. conducted a benchmark analysis of state-of-the-art sentiment analysis methods and ranked the performance of 22 different tools for three different datasets (social network, comments and reviews) [79]. Semantria, developed by Lexalytics, was in the top 5 methods for all of the datasets. It was the second-best method for the dataset of reviews [79]. Considering the availability, accessibility and the type of responses for the questionnaires, the author chose to use this sentiment analysis tool. Semantria gives a sentiment score to a phrase or a sentence by "identifying parts of speech, assigning sentiment score from dictionary, applying the intensifier effect and finally applying their proprietary machine learning techniques" [80], [81]. If needed, the dictionary of sentiment scores can be adjusted to match the specific dataset.

The objective of sentiment analysis of the questionnaire responses was to investigate if one needs-finding technique was more effective in the development of needs statements in terms of the scope, desired change, metric, and choice of words. The questionnaire responses were divided into feedback for method A (Biodesign) and method B (ATNF) for each question. If there was no response from a participant on a specific method for a question the sentiment score of zero was assigned. The author assumed that the responses for method A and method B were mutually exclusive considering the participants were explicitly instructed to provide separate feedback for each method. The sentiment scores for the two methods were compared for the five questions.

4.3.4 Thematic Analysis

Thematic analysis[8] was performed for both sets of data. The author followed the recommended procedure by Braun et al. for thematic analysis [82]. For the questionnaire, a thematic analysis was completed to understand the major themes that emerged from each one of the needs finding techniques and their use. The thematic analysis for the design artefacts aimed to reveal the issues that teams discussed while completing each of the needs-finding techniques. Thematic analysis was done by two researchers for each set of datasets and inter-coder reliability was calculated [75], [76]. The list of codes and their definitions were initially developed by the author and adjusted after another researcher coded 20% of the dataset. The two researchers agreed on a final list of codes and definitions for both the questionnaire responses and the design artefacts (refer to Appendix D).

[8] Thematic analysis is a qualitative method of identifying and analyzing patterns and themes in data.

Chapter 5: Results and Discussion

5.1 Introduction

This chapter provides an overview of the results from the study outlined in chapter 4 and discusses their implications. Section 5.2 covers the results from the three forms of analysis done on the design artefacts. Section 5.2.1 illustrates the results from mapping the need statements to the design artefacts and discusses its implication. Section 5.2.2 covers a more in-depth look at the design artefacts by looking at the results from the thematic analysis and category-based content analysis. Section 5.3 focuses on the feedback provided from the participants in the post-workshop questions. The results from sentiment and thematic analysis are discussed in Sections 5.3.1 and 5.3.2. The limitations of the study are outlined in section 5.4. The general discussion (Section 5.5) provides a synthesis of the different analysis and elaborates on the findings from a follow-up interview as described in Appendices D and E.

5.2 Design artefacts

Three forms of analysis were conducted on the 14 sets of design artefacts (7 from ATNF, 7 from Biodesign). These include: 1) mapping need statement words to the words in the design artefact, 2) category-based content analysis, and 3) thematic analysis.

5.2.1 Mapping need statement words to the design artefacts words

The objective of this analysis is to explore the connection between how each team worked through the various stages of needs finding and how they developed the need statements.

5.2.1.1 Results

To measure how closely the need statements reflected the ideas developed during the first three stages of each needs-finding technique, the number of words in the need statements that appeared in the design artefacts and the total number of occurrences of the need statement words in the design artefacts were used. Two ratios, R1 and R2, were calculated for each set of design artefacts from the ATNF and the Biodesign needs-finding techniques for all groups. Table 5-1 contains the values of R1 and R2 for each individual focus group for both techniques.

$$R1 = \frac{Number\ of\ words\ in\ need\ statement\ that\ appeared\ in\ the\ design\ artefact}{Total\ number\ of\ words\ in\ the\ need\ statement}$$

$$R2 = \frac{Total\ number\ of\ occurrences\ of\ the\ need\ statement\ words\ in\ the\ design\ artefacts}{Total\ number\ of\ words\ in\ the\ design\ artefacts}$$

Table 5-1 R1 and R2 values for Biodesign and ATNF Method for all Focus Groups

Focus Group ID	R1 – Biodesign (%)	R1 – ATNF (%)	R2 – Biodesign (%)	R2 – ATNF (%)
FG1	35.7	35.7	3.4	8.7
FG2	14.3	28.3	6.0	14.5
FG3	33.3	22.7	9.1	4.8
FG4	29.2	24.1	13.5	5.8
FG5	17.4	28.6	2.5	8.2
FG6	29.2	43.8	14.7	18.4
FG7	21.6	25.0	12.3	6.1
Mean	**25.8**	**29.8**	**8.8**	**9.6**
Standard Deviation	**8.1**	**7.5**	**5.0**	**5.0**

The mean values of R1 for the Biodesign and the ATNF method were respectively 25.8% and 29.8%. The mean values of R2 for the Biodesign and the ATNF method were respectively 8.8% and 9.6%. The difference between the two techniques for each one of the ratios is not statistically significant based on a two-tailed, paired t-test. These two ratios indicate the contribution of the ideas from the various stages of needs finding to development of the need statement. The results show that both the Biodesign and the ATNF techniques were equally successful in guiding the design team in developing need statements from the ideas developed in first three stages of each technique.

In order to understand which stage of each needs-finding technique was more closely linked to the words in the need statement, the following ratio was calculated.

$$R3 = \frac{Total\ number\ of\ occurrences\ of\ the\ need\ statement\ words\ in\ a\ particular\ stage}{Total\ number\ of\ words\ in\ the\ need\ statement}$$

Table 5-2 and Table 5-3 contains the values of R3 for each individual focus group for the Biodesign needs-finding technique and the ATNF technique respectively.

Table 5-2 R3 for each stage of Biodesign needs-finding technique

Focus Group ID	R3 for stakeholder analysis (%)	R3 for stating observations (%)	R3 for developing problem statement (%)
FG1	3.6	17.9	17.9
FG2	0.0	9.5	14.3
FG3	12.5	37.5	0.0
FG4	20.8	183.3	33.3
FG5	4.3	13.0	8.7
FG6	4.2	45.8	8.3
FG7	32.4	8.1	8.1
Mean	**11.1**	**45.0**	**12.9**
Standard Deviation	**11.7**	**62.7**	**10.6**

Table 5-3 R3 for each stage of Activity Theory-based Need Finding (ATNF) Technique

Focus Group ID	R3 for stakeholder analysis (%)	R3 for constructing activity systems (%)	R3 for identifying contradictions (%)
FG1	7.1	42.9	28.6
FG2	8.3	35.0	15.0
FG3	0.0	36.4	13.6
FG4	10.3	44.8	3.5
FG5	17.8	35.7	17.9
FG6	40.6	103.1	6.3
FG7	3.6	53.6	17.9
Mean	**12.6**	**50.2**	**14.7**
Standard Deviation	**13.6**	**24.3**	**8.3**

The mean R3 for the stages of developing needs statements (i.e., stakeholder analysis, observations, and problem statement) using the Biodesign technique were respectively 11.1%, 45.0%, and 12.9%. Even though the highest ratio belongs to the stage of stating observations, the difference between these ratios is not statistically significant within the Biodesign technique. On the other hand, the average ratio for the stages of stakeholder analysis, constructing activity systems and identifying contradictions from the ATNF technique were respectively 12.6%, 50.2%, and 14.7%. The highest ratio belongs to the stage of constructing activity systems and there is statistically significant difference between this stage and the other two ones. Constructing activity systems has a significantly higher coverage of the need statement words compared to stakeholder analysis and the contradictions meaning that most of the words used in the need statements come about in the constructing activity system section. It can be deduced that the constructing activity system section allows the team to explore the design space more compared to the other two stages. In addition, the standard deviation for “R3 Stating Observations” is relatively high. However, there is not statistically significant difference between the standard deviations for the two techniques.

5.2.1.2 Discussion

The Biodesign needs-finding technique is well-established and has been used by many design teams. The effectiveness of the needs-finding process for Biodesign is proven through its successful application. The novel ATNF technique allowed the teams to develop needs statements in this study. However, it is important to understand how the process of ATNF leads to development of needs statement. The two ratios (R1 and R2) that connect the words in the need statements to the words in the design artefacts are not significantly different between ATNF and Biodesign. This indicates that the needs statements developed by teams are equally connected to both ATNF and Biodesign needs finding processes.

The words in the need statements were also connected to each stage of the needs-finding process. The analysis indicates that both the “stating observation” and “constructing activity systems” stages contributed most to the words in the needs statement. This means that the design space was most explored during these stages. The value of R3 for constructing activity systems was significantly different from the two other stages, meaning that it had a pronounced role in the ATNF method. This is expected as this is the stage in which the design team maps out the various activities in the problem space.

5.2.2 Category-based Content Analysis and Thematic Analysis

The objective of category-based content analysis and thematic analysis is to investigate the issues and the topics that are covered by the design teams using each one of the two techniques.

5.2.2.1 Results

Using the categories from the PESTLE technique and codes developed through thematic analysis, the following coding structure was developed.

Table 5-4 Categories and Themes for Design Artefacts

Category	Themes
Political	Healthcare provider Non-governmental or non-profit organizations Government Hospital
Economic	Financial support/funding sources Market condition Economically feasible/cost of device Economic status of buyer/receiver of care
Social	Social norms Communication Family and friends
Technology	Quality/reliability of Technology Manufacturing Training Developers Specific instrument Use Maintenance Technical design requirements
Legal	Device Regulation Laws/general regulations
Environmental	People Physical Time
Clinical	Training Medical condition Physician Other clinical staff Patient
General	Supply chain Low-resource setting System level issues Access to healthcare

The coding scheme, including the definition of each code, was used by two researchers to co-code the data. The coders ensured that the coding was mutually exclusive between the categories. In other words, if a phrase was coded as “economic”, it would not be coded into any other category. The percentage agreement between the coders was 97.09% and the kappa coefficient was 0.34. The

percentage agreement is high; however, the kappa coefficient indicates a fair agreement between the two separate analyses [75].
The aim of conducting thematic analysis on the design artefacts was to understand the type of issues the design teams covered as they completed each technique. Table 5-4 presents an overview of all the themes and the categories for the design artefacts. The definition of each code and examples are given in Appendix D.1.

The percentage coverage of each category was calculated for each set of design artefacts for both techniques. Table 5-5 and Figure 5-1 show the mean percentage coverage for each category for all the focus groups for each needs-finding technique. Notably, the rows in Table 5-6 do not add up to 100% because a set of design artefacts was not fully covered by these specific categories. Using a two-tailed, paired t-test, it was clear that the difference between the percentage coverage is not statistically significant for any one of the categories. The technological and the technical dictionaries had the highest percentage coverage. The mean percentage coverage for the ATNF technique is slightly higher for the political, legal and social categories. However, the mean percentage coverage for the economic, environment, technical and clinical categories is higher for the Biodesign method.

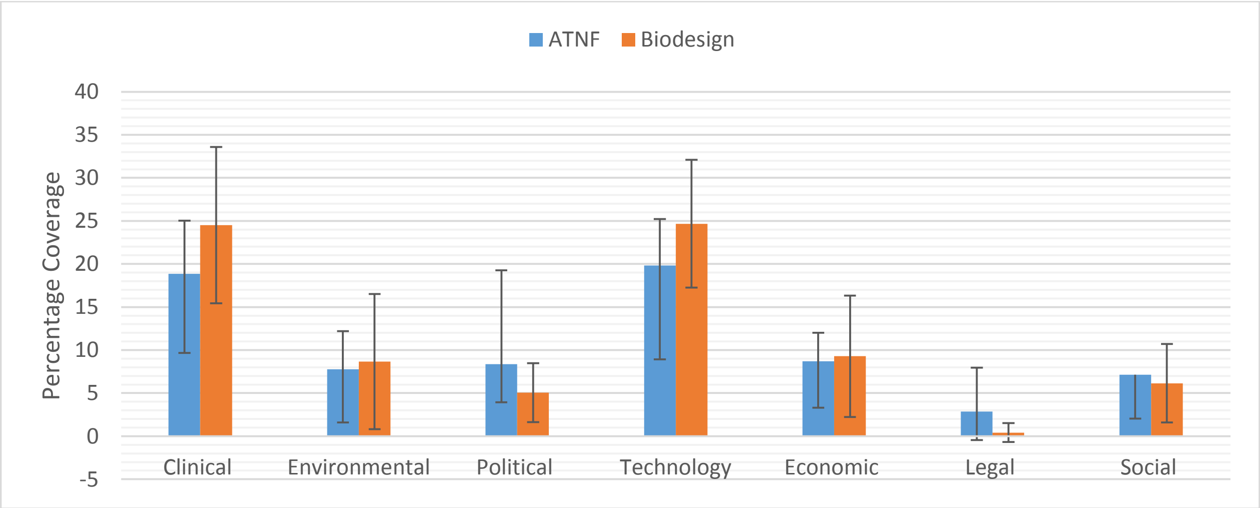


Figure 5-1 Mean Percentage Coverage and Standard Deviation for Each Category

Table 5-5 The Mean and Standard Deviation for Percentage Coverage of each Category for Design Artefacts

Percentage Coverage (%)	Clinical	Environmental	Political	Technological	Economic	Legal	Social
ATNF	18.9 ± 9.2	7.8 ± 6.2	8.4 ± 4.4	19.8 ± 10.9	8.7 ± 5.4	2.8 ± 3.3	7.1 ± 5.1
Biodesign	24.5 ± 9.1	8.7 ± 7.8	5.0 ± 3.4	24.7 ± 7.4	9.3 ± 7.0	0.4 ± 1.1	6.1 ± 4.6

5.2.2.2 Discussion

The results from the category-based analysis indicate that both the ATNF technique and the Biodesign needs-finding technique facilitate discussion of a diverse set of issues in the needs-finding process. The ATNF technique provides a more explicit means to promote this discussion as highlighted in the questionnaire analysis (Section 5.3). However, that is not represented through the design artefacts. Even though the category-based analysis gave us a useful indication of the issues covered in the design artefacts, it is important to note that it was challenging to interpret and code the artefacts. Notably, the kappa coefficient only indicates a fair agreement between the two coders, indicating that it was challenging to get a highly consistent coding of the categories.

The themes show what types of topics were discussed using both of the techniques. Even though the category-based analysis does not indicate a significant difference between the coverage of these topics for the two techniques, it is important to note that these topics were covered by both of the techniques, indicating the efficacy of ATNF. The sub-themes can be used to have more explicit prompts for the ATNF technique. For example, for the technical rules, instruments and division of labour, the question can explicitly ask about technical design requirements, usability condition and manufacturing process.

5.3 Questionnaire Analysis

The following two sections describe the results from the sentiment analysis and the thematic analysis on the questionnaire response from the 30 participants.

5.3.1 Sentiment Analysis

The aim of this sentiment analysis was to assess the effectiveness of each needs-finding technique with respect to developing a need statement based on participants' perspectives.

5.3.1.1 Results

The Semantria sentiment scores for the questionnaire feedback on the Biodesign technique were compared to the ATNF technique responses. It is noteworthy that Semantria gives sentiment scores between -1 and 1. Table 5-6 summarizes the results. The average sentiment score is higher for the ATNF technique across all questions. After applying the Bonferroni correction for multiple comparisons, the p-value needs to be less than 0.01 for a two-tailed, paired t-test. The difference is statistically significant for Q1 and Q4. The average sentiment score is not statistically significant for Q2 and Q5. However, considering the Bonferroni correction is highly conservative, it can be said that the average sentiment toward ATNF trended positive. The difference between the sentiment scores is not statistically significant for Q3.

The sentiment scores were adjusted in the Semantria dictionary manually. The new sentiment scores were assigned based on existing scores for similar phrases. Appendix C includes the summary of the sentiment scores given for Question 1 as a sample.

Table 5-6 Average Sentiment Score for Questionnaire Responses for the Biodesign and ATNF Techniques

Question	Biodesign Technique Mean Sentiment Score	ATNF Technique Mean Sentiment Score	p-value
1. How did you use each one of the tools to identify the appropriate scope for your need statement?	0.104	0.467	0.003
2. How did you use each one of the tools to come up with context-specific words for your need statement?	0.117	0.276	0.02
3. How well did each one of the tools help you define an appropriate metric?	0.126	0.240	0.3
4. How well did each one of the tools help you define a desired change for your need statement?	0.0809	0.390	0.001
5. Do you have any other comments about the two need finding techniques? Please elaborate.	0.140	0.399	0.02

5.3.1.2 Discussion

The participants had a positive sentiment toward both of the techniques for questions 1 and 4; however, they thought that the ATNF technique was more effective in developing an appropriate scope and identifying a desired change. The participants mentioned that the ATNF technique allowed them to think through more information and integrate it to arrive at an appropriate scope. They also thought that the ATNF technique was more helpful in identifying a desired change through determining existing contradictions. The thematic analysis of the participant feedback thoroughly explains why the participants had a more positive opinion toward the ATNF technique on scope and the desired change. Based on the responses for question 2, the participants had a more positive sentiment toward the capability of both methods to help them find context-specific words for their needs statements. The responses indicate a more positive trend toward the ATNF technique; however, there is not a statistically significant difference. The thematic analysis elaborates on how each technique allows the design teams to derive context-specific words. Question 3 on the development of a metric has a relatively low sentiment score for both of the needs-finding techniques, indicating that it was the most challenging part of writing a need statement. This is also highlighted in the results from the thematic analysis. Both of the techniques did not have an explicit means of defining a metric, and this could be considered for future improvements of the ATNF method.

5.3.2 Thematic Analysis

The following section presents an overview of the results for the thematic analysis of the questionnaire responses and discusses its implications.

5.3.2.1 Results

The thematic analysis was done by two coders using a scheme that was initially developed by one of the coders and then further improved through discussion. The full list of codes and their description is presented in Appendix D.2. The percentage agreement between two coders is 96% and the kappa coefficient is 0.73, indicating a high level of agreement [75].

The responses indicate that the participants recognized the process for both the ATNF technique and the Biodesign needs-finding technique. For the Biodesign technique, participants highlighted how a detailed analysis of the stakeholders allowed them to make the observations and problem statements that led to the development of their need statements. For the ATNF technique, the responses highlighted that constructing activity systems allowed them to look at different aspects of the design space; identifying the contradictions helped to synthesize the information to develop the need statements. In the following, the author discusses the results of the thematic analysis for each of the five questions included in the post-workshop questionnaire. *Method A* refers to the Biodesign technique and *Method B* refers to the ATNF technique.

Question 1 - How did you use each one of the tools to identify the appropriate scope for your need statement?

For Method A participants indicated that identifying stakeholders, stating observations and developing problem statements allowed them to define the scope. Some responses emphasized that the method encouraged brainstorming and discussion, which helped with developing scope. Others mentioned that the linear process allowed them to identify scope. Few responses noted that there was no specific way for identifying scope, and that it was difficult to see where the scope ends. For Method B, responses highlighted identifying and developing activity systems and developing contradictions allowed the team to define a scope for their need statement. The responses emphasized that Method B was used to break down various ideas in a structured way to understand details of the problem. Even though a lot of details were worked through, the method allowed the teams to synthesize the information to define scope.

Question 2 - How did you use each one of the tools to come up with context-specific words for your need statement?

All the stages of Method A aided in development of context-specific words, specifically *cycle of care* and *problem statement*. The logical progression of Method A was highlighted. The technique also allowed the team to brainstorm different aspects of the problem and create a discussion. Similarly, all stages of Method B contributed to the development of context-specific words. Development of activity systems and identification of contradictions were specifically highlighted. Participants noted that Method B allowed development of the context-specific words by prompting the team to lay out the necessary information by providing “quick cues”, breaking down the ideas, organizing the information and brainstorming. A response noted that “Method B made explicit some implicit knowledge that aided in finding specific words”.

Question 3 - How well did each one of the tools help you define an appropriate metric?

There is a split in opinion about how well each technique helped in defining appropriate metrics. The responses indicate that some participants struggled with identifying a metric using both of the techniques, and on the contrary other participants found both techniques to be effective. The participants who thought Method A was more effective mentioned that it was easier and more straightforward to identify metrics by iteratively going through the stakeholder analysis, observations and problem statement stages. However, some also indicated that it was not easy to connect the ideas discussed in these stages to a particular metric. On the other hand, the participants thought Method B was effective because it allowed them to structurally lay out the necessary information, think of the technical and non-technical aspects and make connections between various aspects. These all helped in identifying the appropriate metric. Particularly, identifying the objective for an activity system and then determining contradictions was helpful in defining the metric. However, a number of participants indicted that it was challenging and not intuitive to use the technique to determine a metric.

Question 4 - How well did each one of the tools help you define a desired change for your need statement?

The responses indicated that both Method A and Method B allowed the teams to identify a desired change. Desired change was mainly determined through development of problem statements for method A. The responses noted that the process for method A was easy to use and led to the desired changes in a focused way. However, responses also noted that Method A did not allow them to explore different aspects of the desired change. For Method B, the responses heavily emphasized that contradictions were helpful in identifying a desired change. Method B considered more aspects of the design space, including “societal” and “situational” factors when determining the desired change. Method B also allowed the participants to have a more in-depth understanding of the desired change.

Question 5 - Do you have any other comments about the two needs-finding techniques? Please elaborate.

Overall, the participants indicated that they enjoyed the workshop and thought that both of the techniques were effective in analyzing the needs. The participants noted that Method A was easier to understand and use; however, it was less structured, and it was challenging to synthesize the information. Method B was more structured, and that feature allowed the participants to acquire a more detailed understanding of the problems. The terminology was harder to understand and it took longer for the teams to work through learning the method.

Three main themes emerged through the responses to the questionnaire: usability, method of analysis and integrating context and stakeholder input. The three themes and their sub-themes are illustrated in Table 5-7. The number of references coded to each sub-theme by the primary coder (the author) per technique is also noted in Table 5-7.

The two sub-themes “bringing in context” and “bringing in stakeholders” capture how each of the techniques considered context and stakeholders in development of the need statement. The number of references for the “bringing in context” code was 4 and 10 for Methods A and B, respectively. For Method A, context was considered through brainstorming of issues about stakeholders. For Method B, responses indicated that context was incorporated through a structured method that asked the participants to lay out all the necessary information from multiple perspectives and dimensions including societal and situational factors. Contradictions were developed based on this information to determine context-specific need statements. The number of references for “bringing in stakeholder” code was 14 and 17 for Methods A and B, respectively. Participants noted that Method A asked them to analyze the stakeholders to develop the scope and the metric for the needs statements. Understanding stakeholders was critical for use of this technique. Some noted that Method A focused on one or two key stakeholders. For Method B, the participants also looked at stakeholders through a structured approach. The responses emphasize how multiple stakeholders were considered through this method, and this allowed them to consider the whole system more effectively.

Four codes, “ease of use”, “time”, “familiarity with technique”, and “use of previous knowledge”, provide an understanding of the usability of each technique. The responses on “ease of use” were split evenly between the two techniques. Some participants thought that method A was easier to use because it was more linear and they were more familiar with this technique, as highlighted from the six references to Method A for the “familiarity with technique” code. Some noted that Method A was unstructured and that made it difficult to reach a conclusion and define the scope of the problem. Participants were also able to execute Method A faster; however, the teams covered fewer details in the process. The structure provided by Method B was helpful according to some participants and it allowed them to develop a need statement “organically and smoothly”. However, the terminology for Method B was abstract and harder to understand according to some of the responses. Executing Method B took more effort and time. However, the technique elicited more details and comprehensive analysis. Some participants recognized that they had more background information about one of the design projects in the workshop. Few noted that having more background knowledge would also help with execution of both of the needs-finding techniques.

Method of analysis for each technique is captured within three codes, “structure of analysis”, “level of analysis” and “thinking style”. The number of references to each code is shown in Table 5-7, and the number of references to Method B is higher compared to Method A. For both of the methods, participants recognized the structure of the techniques. For Method A, responses emphasized the role of cycle of care analysis in developing the need statements. In addition, the participants highlighted that the process was straightforward to follow and it did not have an explicit structure; therefore, iterative brainstorming and discussion were critical to development of the need statements. Even though Method A was effective in achieving an understanding of the bigger picture, the participants remarked that they were not able to cover many details using this method. The triangular activity system framework and identification of contradictions were highlighted by many participants as key parts of Method B’s process. The activity systems allowed the participants to break down the existing issues and forced them to consider more issues. The contradictions allowed the team to collate the information and made it easier to draw conclusions. The participants recognized that this structured method pushed them to think more in-depth about the problem and better support their need statements. Some participants remarked that Method B allowed them to "think outside of the box" and "make explicit some implicit information about the problem".

Table 5-7 Thematic Codes for Questionnaire Responses and their Description

Theme	Sub-theme	Description	Method A (Number of references)	Method B (Number of references)
Usability	Familiarity with technique	Any indication of familiarity with the needs-finding technique	6	0
	Ease of use	Perspective on how easy it was to apply and use each one of the needs-finding techniques	14	15
	Time	Perspective on how long it takes to go through each technique	4	4
	Use of previous knowledge	Any references to use of previous knowledge in the analysis	6	2
Method of analysis	Thinking style	Perspective on how the participants thought through the problem	16	27
	Structure of analysis	Perspective on overall structure and steps that the participants follow for this need analysis	19	40
	Level of analysis	Perspective on depth understanding they achieved	22	38
Incorporating context and stakeholders	Bringing in stakeholders	Perspective on how stakeholder input is brought in the technique	14	17
	Bringing in context	Perspective on how context is analyzed and understood	4	10

5.3.2.2 Discussion

The responses to the five questions indicate how well each technique facilitates the process of need statement development. The questions considered the scope, choice of context-specific words, metric and the desired change. The participants had a positive sentiment toward both techniques. However, they noted that the ATNF technique was more effective in developing an appropriate scope and identifying a desired change.

Contrary to the Biodesign technique, which focuses more on stakeholder involvements, the ATNF technique also explicitly incorporates elements of context-aware design as highlighted in the thematic analysis. The ATNF technique has a more structured approach, which allows designers to have a more comprehensive understanding of the needs. The Biodesign technique is more linear and less structured, which means that the participants brainstorm and discuss to come up with the need statement. The Biodesign technique is easier to learn and use. However, the cues and frameworks for the ATNF technique were helpful in facilitating the thinking process for the design teams.

5.4 Limitations

One of the main limitations of this study is that there are currently no standard ways of comparing the quality of need statements and the process of needs finding. For the purposes of this research, the study used the four elements of need statements identified by the Biodesign process: scope, metric, context-specific words and desired change. Even though the Biodesign process is well-recognized, these four factors are not the only elements that need to be considered when looking at the quality of need statements and the needs-finding process. The thematic analysis of the design artefacts and the questionnaire provide some metrics that could be considered for future research. For example, the diversity of issues discussed in the needs-finding process, the depth of analysis, the ability of a particular technique to synthesize information could be studied.

Creating quantifiable measures for qualitative data in sentiment and category-based analysis has its inherent limitations [72]. There is a bias with coding and assigning sentiment score. In this research, two coders were used to reduce coder bias, and the Lexalytics' Semantria software has well-established algorithms to minimize bias. In addition, quantifying qualitative data creates abstractions. Some information might be taken out of context and some might be completely missed in the process of analysis.

Finally, even though the study had 30 participants, they were split into 7 teams. This only provides 7 sets of data for the design artefact analysis. More participants would have helped to strengthen the analysis. In addition, the groups had only a limited time to learn and use each technique. They were also more familiar with the Biodesign technique, considering it is more conventional. The extent of each team's analysis also depended on the knowledge of the group. Some teams did not know as much about the socioeconomic or clinical issues involved.

5.5 General Discussion and Summary

The author used multiple forms of analysis to investigate the two sets of data (design artefacts and questionnaire responses) from this study. This section provides a summary of the results and provides a comparison across various forms of analysis.

The results from mapping of the need statement words, category-based content analysis and thematic analysis of the design artefacts are consistent. The contribution of the design artefact words to the need statements is the same for both the ATNF and the Biodesign needs-finding techniques. Similarly, the categories that are covered by each set of design artefacts is consistent between the two techniques. The analysis of the design artefacts indicates that the ATNF technique matches the performance level of the Biodesign technique. However, the results do not indicate that one technique performs significantly better.

The results from the sentiment and thematic analysis of questionnaire responses are also consistent internally. The sentiment scores for determining appropriate scope and desired change are significantly more positive for the ATNF technique. The thematic analysis supports this by revealing that the ATNF technique allowed the design teams to consider more contextual factors, think alternatively and provide a more in-depth analysis. The sentiment score for identifying context-specific words is more positive for the ATNF technique. The participants highlighted that the ATNF forced them to explicitly develop their implicit assumptions about stakeholders and context. This allowed them to develop more specific words for their need statements. The sentiment score for developing a metric for each need statement was equally low for both of the techniques. Participants were divided in their opinion about which technique was more helpful in defining a metric; however, overall neither technique provided an appropriate means for metric identification. Even though the Biodesign technique was more familiar and user-friendly, the participants had a more positive sentiment toward the ATNF technique.

The analysis results from the two data sets, design artefacts and questionnaires, complement each other. The design artefact analysis indicates that the two needs-finding techniques are similar in performance. However, the questionnaire analysis reflects the user response for usability of each technique and the quality of the need statements. The strengths of the ATNF techniques are better highlighted in the questionnaire responses. The ATNF does not perform better than the Biodesign technique according to the design artefact analysis. That can be partially due to limitations of the analysis and the size of the study. However, the analysis from both sets of data provides a holistic understanding of the advantages and disadvantages of ATNF and the Biodesign techniques.

Based on the results of the analysis in this Chapter, reflections on each application of ATNF (Appendix A) and the thematic analysis from the follow-up interview (Appendix F), there are four main points of improvement for the ATNF technique. Firstly, the terminology for the ATNF technique needs to be simplified and clarified. Specifically, the terms *objective* and *outcome* need to be distinguished. The objective is the motive of the stakeholder for doing an activity. The outcome is change of state of any elements of the activity systems. The term *rules* can be replaced by *conditions and constraints*. Secondly, the prompt questions for each element of the activity system need to be clarified to eliminate misunderstandings about the technical and non-technical sections. The themes and categories for the design artefacts can provide a strong basis for creating these questions. Thirdly, the scope of an activity system needs to be more specific. This can be done by highlighting that both the subject and the objective are well-defined. Adding another activity system element, *Input*, could allow a design team to narrow their scope by defining the status quo prior to the activity. Finally, the contradictions need to be defined more clearly by specifically highlighting the contradicting elements. Identification of contradictions can also be more systematic by ensuring to first analyze within and then between activity systems.

Chapter 6: Conclusion

This thesis was motivated by the challenge of designing, implementing and delivering medical devices to address healthcare problems in Low and Middle Income Countries (LMIC). From the investigations conducted by WHO and USAID, it has become clear that engineering teams need to have a more comprehensive understanding of design spaces in the healthcare environment of LMIC early in the medical device design process [35]. A survey of existing needs-finding tools showed that there is an opportunity to improve the techniques so that socioeconomic needs are better integrated with clinical and technical needs.

In order to leverage this opportunity, this thesis investigated existing theories that consider socio-technical issues (refer to Chapter 2). As a result, Cultural Historical Activity Theory emerged as the most promising construct on which to base a novel needs-finding technique for medical device development in LMIC. Chapter 3 provides a detailed description of the resulting ATNF technique and illustrates a case study in which the technique is applied. To prove the efficacy of this novel technique, the author conducted a study with engineering design teams and compared the efficacy of the ATNF technique with a more conventional needs-finding tool, the Stanford Biodesign process (refer to Chapters 4 and 5).

The main contributions of this thesis are the development of the Activity Theory-based Needs-finding technique and the demonstration of the technique's effectiveness in comparison to the Biodesign needs-finding technique for engineering student medical device development projects for LMIC. In particular, this thesis addressed the following two questions: a) Can ATNF be used for needs-finding for medical device development? (recapped in Section 6.1 below); b) How does the ATNF technique perform compared to the Biodesign needs-finding technique? (Section 6.2). The thesis then addresses how the ATNF technique can be improved based on this research (Section 6.3). This chapter concludes by highlighting the recommendations for future work (Section 6.4).

6.1 Can ATNF be used for needs-finding for medical device development?

The case study of the 3D-PrintAbility project in Section 3.4 is the first illustration of how ATNF can be used to develop need statements for an existing healthcare technology project within LMIC. This application of ATNF demonstrated that modified activity system frameworks can be used to describe an existing healthcare challenge. The contradictions between these activities were then used to integrate social, economic, political, clinical and technical parameters to develop need statements. Furthermore, the study outlined in Chapter 4 illustrates how seven biomedical engineering teams with no prior exposure to ATNF learned how to use this technique on a medical device design problem. The results from this comparative study supported that the ATNF and the Biodesign needs-finding processes equally contributed to the need statements that were developed. In addition, the design artefacts, the ideas captured in writing by each team using each one of the needs-finding techniques, were compared using category-based content analysis. This investigation showed that the teams equally covered topics in clinical, technical, political, legal, environment, social and economic categories. This provides evidence that the efficacy of the ATNF method is comparable to the Biodesign method.

6.2 How is the ATNF compared to that of the Biodesign needs-finding technique?

The main hypothesis of this thesis was that compared to the Biodesign needs-finding technique, the ATNF technique would allow an engineering design team to develop a more comprehensive understanding of the problem and subsequently improved need statements. The category-based content analysis did not show any difference between the design artefacts produced from the use of the two techniques. However, the feedback from the participants on the quality of the need statements and the process of developing them lead to performing another level of analysis.

The participants assessed their need statements based on scope, context-specific words, metric and desired change. Results from the sentiment analysis indicated that the ATNF technique was more effective in developing need statements that have an appropriate scope and in identifying a desired change. Both of the techniques were equally effective in developing context-specific words. The participants struggled with determining a metric for need statements for both of the techniques.

As expected, the Biodesign needs-finding process was more familiar to the engineering design teams. According to the design teams, the process of identifying stakeholders, stating observations, developing problem statements and defining need statements was linear. This process was also less structured in comparison to the ATNF technique. Therefore, the teams emphasized the importance of using brainstorming and discussion for the development of their needs statements. Even though the teams found it easier to learn the Biodesign method, they thought it was difficult to identify appropriate desired changes and the scope of the problem using this process. The teams did not get a chance to analyze the problem in-depth and found it challenging to synthesize the information they had. The ATNF technique was more challenging to learn, especially considering the larger set of terminology used in the needs-finding process. However, the structure of the activity systems pushed the design teams to consider multiple perspectives and incorporate contextual factors. The structure of an activity system pushed the teams to think "outside of the box" and consider factors beyond the technical or clinical elements. Identifying contradictions between and within activities was also helpful in identifying desired changes and synthesizing the information in the design space. The ATNF method allowed the teams to explicitly think through their implicit assumptions and understanding of the problem.

6.3 How can the ATNF technique be improved?

Based on the observation of the use of the ATNF method and the feedback provided, there are five primary ways in which ATNF method could be improved.

1. The definitions of the *objective* and the *outcome* need to be further clarified and improved. *Objective* is what motivates a subject to take part in an activity. The *outcome* is the change in status of the subject, instrument, the community, the rules and the division of labour because of the activity.
2. The term *rules* is ambiguous. The phrase *constraints and conditions* can be used instead of rules. The non-technical rules can be divided into social, economic, political, legal and environmental subcategories. More specific questions and prompts can also be developed for both the technical and non-technical rules based on the themes observed in the design artefacts.

3. *Input* can be added as a new element to an activity system. The input would describe the status of the subject prior to the activity. For example, this can describe the medical condition of a patient.
4. An activity system needs to be specific and focused. An activity system must have a subject (an individual or an organization) that has a clearly defined objective. There can only be one objective for one activity system. For example, a hospital cannot be a subject, whereas the procurement department of a hospital can be a subject. In addition, elements of an activity system need to be clearly outlined. For example, the instruments (physical or non-physical) need to be described in detail.
5. The contradictions need to be identified and categorized in a more systematic way. The teams can identify contradictions starting from within an activity system and broadening to look between activity systems.

6.4 Recommendations and Future Work

The findings from this thesis show that the ATNF technique is a plausible needs-finding method and that it provides a powerful means for laying out and synthesizing contextual information in the design space for medical device development for LMIC. In light of these findings, a number of questions need to be further investigated. How would an expert medical device development team use ATNF? Can this technique be extended to develop detailed requirements for engineering design? How can this method be used in tandem with other needs-finding techniques? Can teams use this technique independently over time? ATNF provides specific strengths that can be advantageous for medical device development in LMIC. However, it is important to use this tool in tandem with other needs-finding tools.

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Appendices

Appendix A Transcribed Design Artefacts

The following are all the design artefacts that were created by the teams during the workshops.

A.1 Focus group 1 – ANTF

Stakeholder Analysis

- Doctors – otolaryngologists
- Engineers-in-Scrubs
- Competitors
- Patients
- Friends and family
- Speech therapists
- Healthcare providers
- Health Canada and governing bodies

Based on this stakeholder analysis the team decided to focus on two activities. The first activity is the healthcare provider helping the patient with speech recovery following laryngectomy and the second activity is the patient trying to learn to verbally communicate following the surgery.

Constructing Activity Systems (AS)

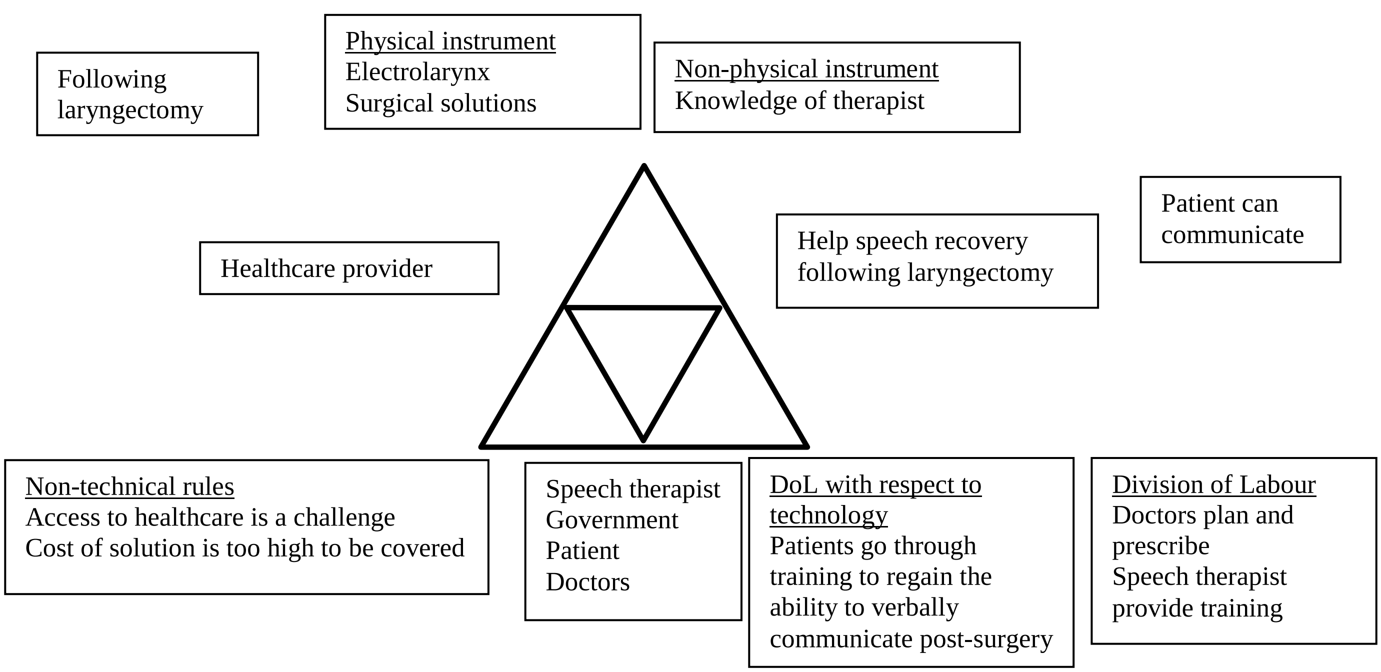

Figure 6-1 Activity System 1 for Focus Group 1

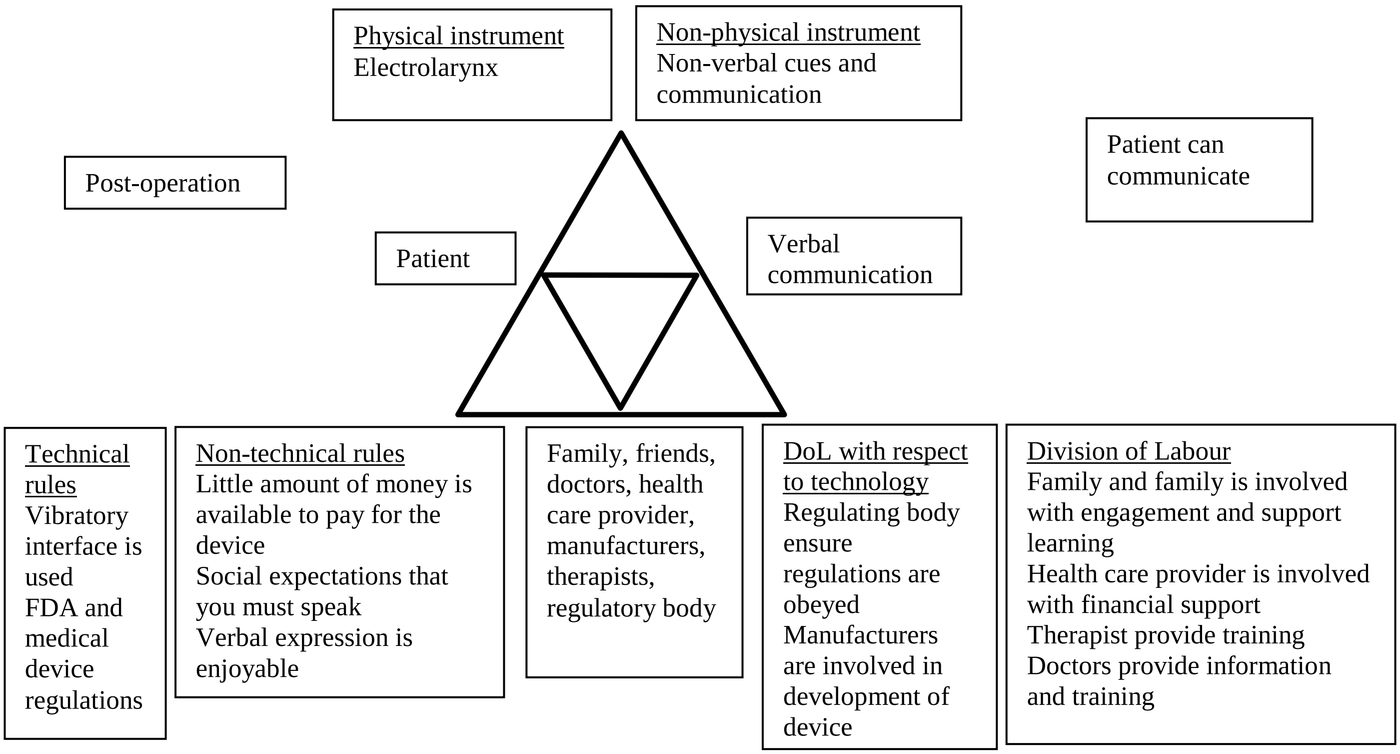

Figure 6-2 Activity System 2 for Focus Group 1

Identify Contradictions

- Contradiction between objective of AS1 and non-technical rule for AS2 - Best solutions isn't provided to patient
- Not fully captured within these two activity systems - Government's lack of funding for healthcare cause higher long term costs
- Not fully captured within these two activity systems - Little money is available but multiple sources of possible money is available.
- Contradiction between non-technical rule and existing non-physical instruments - Societal expectations of verbal communication despite alternatives.
- Contradiction between the non-technical rules in AS1 and 2 and DoL with respect to technology in AS2: Lots of people cannot afford current option but manufacturer does not make cheaper and effective alternative.

Develop Need Statement

Target audience: post-op low resource patients
Desired change:
Provide more cost effective verbal communication solution to patients
Change social expectations
Metrics: increase number of patients that can communication in like with societal expectations

Need statement: Need to provide an affordable method of verbal communication to increase the number of post-op patients in low resource settings that can communicate in line with societal expectations.

Reflection - Problems with existing application:

- Technical rules are not fully captured. Some of the technical rules could have involved the specifications of existing physical instruments and how they allow the user to speak.
- Healthcare provider is too broad of a subject for ATNF purposes
- Some of the contradictions are not reflected from the existing activity systems

A.2 Focus group 1 – Biodesign

Table 6-1 Biodesign Steps for Focus Group 1

Stakeholder analysis	State observations	State problem statements
Cycle of care Dr. Leah (& her team) Other Doctors Neurologists → possible brain problem Otolaryngologists → otolaryngologist diagnoses Family Doctors → first one to identify problem and send to specialists. Patient (with dizziness, possible other ailments). Family members → to help patient outside the hospital St. Paul's Hospital Sterilization team (@ hospital) Engineers in scrubs Money flow BME engineering team and those who made the cheap option Healthcare providers: Providence health, VCH Competitors Manufacturers	Benign positional vertical is less relevant to the problem Device needed for "unknown causes". Can't watch patient the whole time, need to put patient into 'positions' in order to induce vertigo Needs to be done in the dark (w/ no visual cues) Note: we can process the video we take and therefore extend the scope of the project Note: we could get eye movement info from multiple possible sources: Video, Electric dipole Dr. Leah said must have accuracy +/- 5 degree Patents want cheap, durable, comfortable, easy to use (my grandpa couldn't set up St. Paul's version) BME Engineering team is indirectly affected positive or negatively by our work Autofocus/ other power source options Patients know when a vertigo attack is occurring.	Doctors are unable to see what they want to see when they want to see it. Patients' vertigo attacks are unpredictable. Cost vs. quality of the device is unbalanced Current solutions are either too expensive for St. Paul's to loan to patients or too low quality to be reliably used Doctors are unable to see patient eye movement during a vertigo attack due to unpredictability of occurrence

State Need Statements

A method for obtaining eye movement data during vertigo attack for a physician, which can be obtained reliably and remotely, from the hospital, affordably, and easy to use.

A.3 Focus group 2 – ATNF

Stakeholder Analysis

- Patients
- Surgeons
- Nurses
- Hospital operators/purchasers
- Manufacturer
- Developers
- Patient under anesthesia
-

Constructing Activity Systems

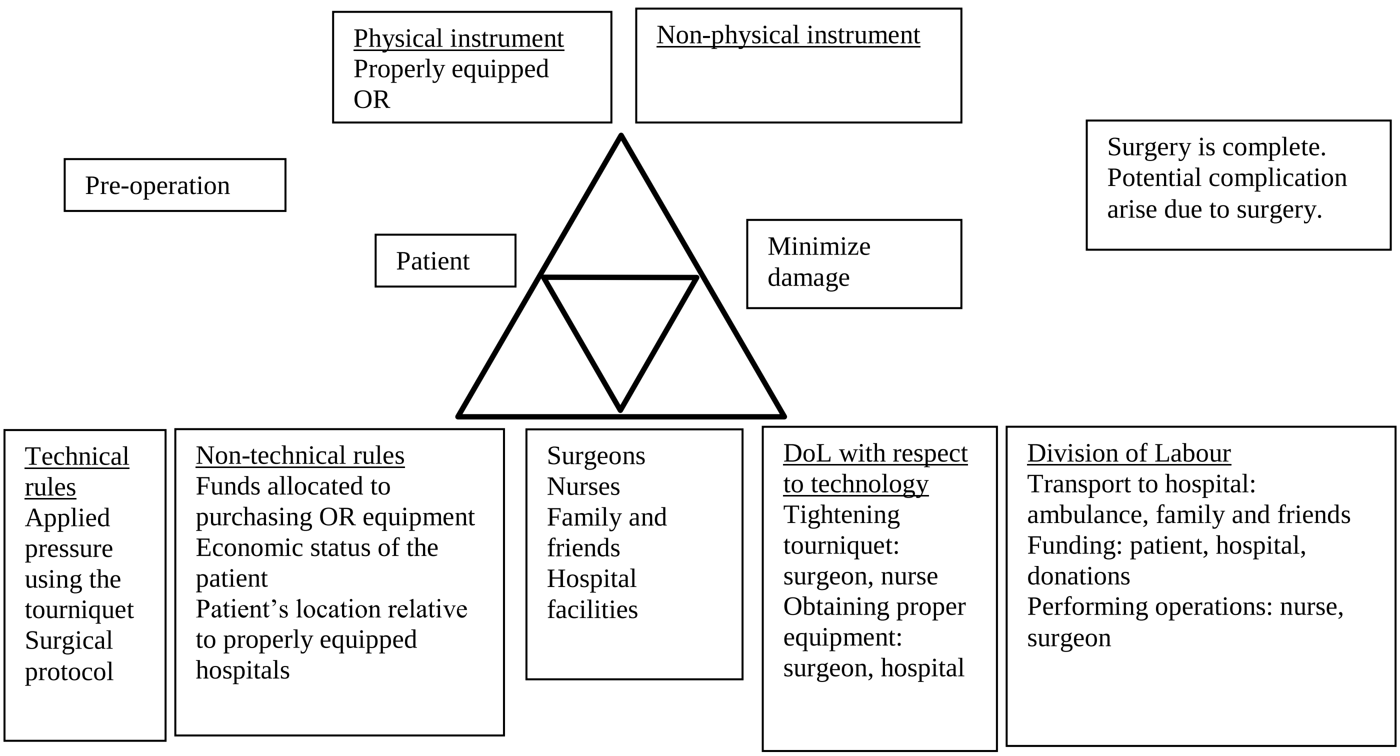

Figure 6-3 Activity System 1 for Focus Group 2

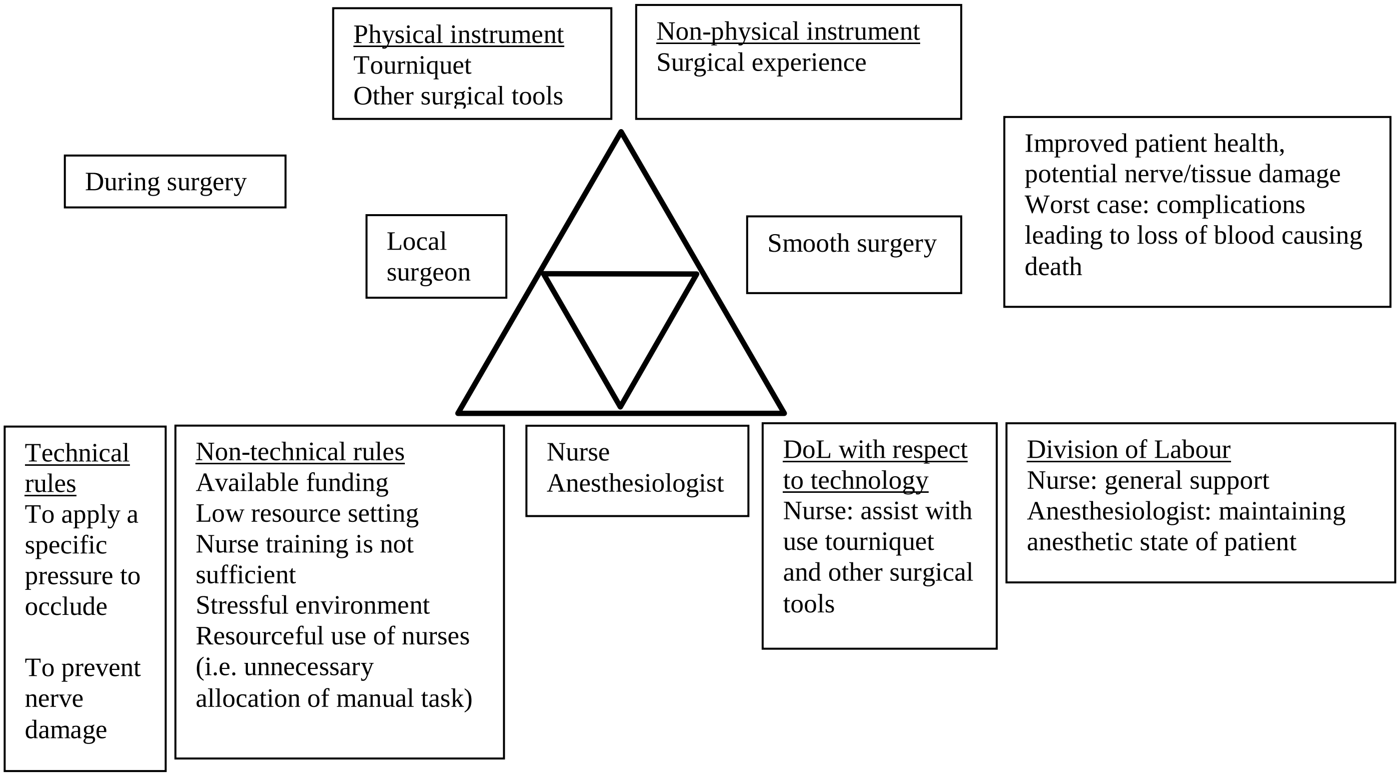

Figure 6-4 Activity System 2 for Focus Group 2

Identify Contradictions

- Surgical outcome may outweigh risk of nerve/tissue damage – contradiction between objective of the patient which is to minimize damage and potential complications from the surgery.
- Different priorities between patient and surgeon
- Makeshift tourniquet does not apply desired pressure – contradiction between existing equipment do not meet the required technical rules
- Poorly trained nurses might not be able to perform specific pressure application- conflict between a non-technical and technical rule
- Using hand pump tourniquet requires attention, annoying for surgeon and nurse – this is not necessarily captured in the activity systems. Potential conflict between stressful environment (non-technical rule) and division of labour with respect to technology)
- Want best treatment, don't have much money – the contradiction between desire of the patient and their socioeconomic status
- Surgeon wants to treat as many patients as possible - the conflict between the surgeons motive and the available resource (non-technical rules)

Develop Need Statement

- A method of occluding blood that

    - Does not require extra personnel
    - Can apply the desired pressure
    - Is economically feasible for the setting
    - Does not cause damage to patient
- Metrics
    - Reduce the number of patients who are injured by improperly tightened tourniquets in low resource hospitals
    - Occlude blood for duration of surgery without causing damage

Reflection - Application of AT:
The patient is involved in the activity of going to the appropriate healthcare facility. The patient wants to heal without causing any other damage. In order for this to happen the patient needs to go to a hospital that is properly equipped. The tasks need to be followed appropriately by each one of the various stakeholders. The technical and non-technical rules have been outlined. They are relevant.

Reflection - Potential shortcomings:

- Looking at the activity it can be argued that "minimize damage" is not the real motif of the patient. The patient wants to get back to doing their activities of daily living. However, this is something that can only be clarified with very close engagement with the patient. Currently, minimize damage is equally possible form of the objective. One of the shortcomings of this study is that the teams did not have very through interactions with any of the stakeholders. Potentially, it would even be better to construct these activities in collaboration with the patients.
- The DoL of applying the tourniquet is not part of the activity of patient reaching to the appropriate operating facilities. It is important that the hospitals has the proper equipment and that all the staff are following the appropriate surgical facilities. This was an error in developing the AS. It is important to keep the rules and DoL very specific to the activity at hand.
- The second activity has much more of a focused scope. This is much better for the sake of this technique because it allows the design team to be more specific. If the team had more time they could have gone into more details. The experience level of the team with the technique would have also been helpful in this scenario.

A.4 Focus group 2 – Biodesign

Table 6-2 Biodesign Steps for Focus Group 2

Stakeholder analysis	State observations	State problem statements
Patient Physician Hospital/procurement Manufacturers Us!	Patient has bladder issues Referral to specialist Physician performs scope Treatment proceeds Power goes out! Procedure is delayed Less patients receive treatment Scope light is wall powered, low efficiency. Scopes provided by donations and international physicians	Power goes out or power surges Procedure is delayed

Need statement

A method to reduce the number of delays caused by power outages, and maintain illumination during outages and surges for endoscopes

A.5 Focus group 3 –ATNF

Stakeholder Analysis

- Hospital
- Surgeon
- Patient
- Nurse
- Anaesthesiologist
- Manufacturer
- Person responsible for repair and maintenance
- Insurance company
- Government
-

Constructing Activity Systems

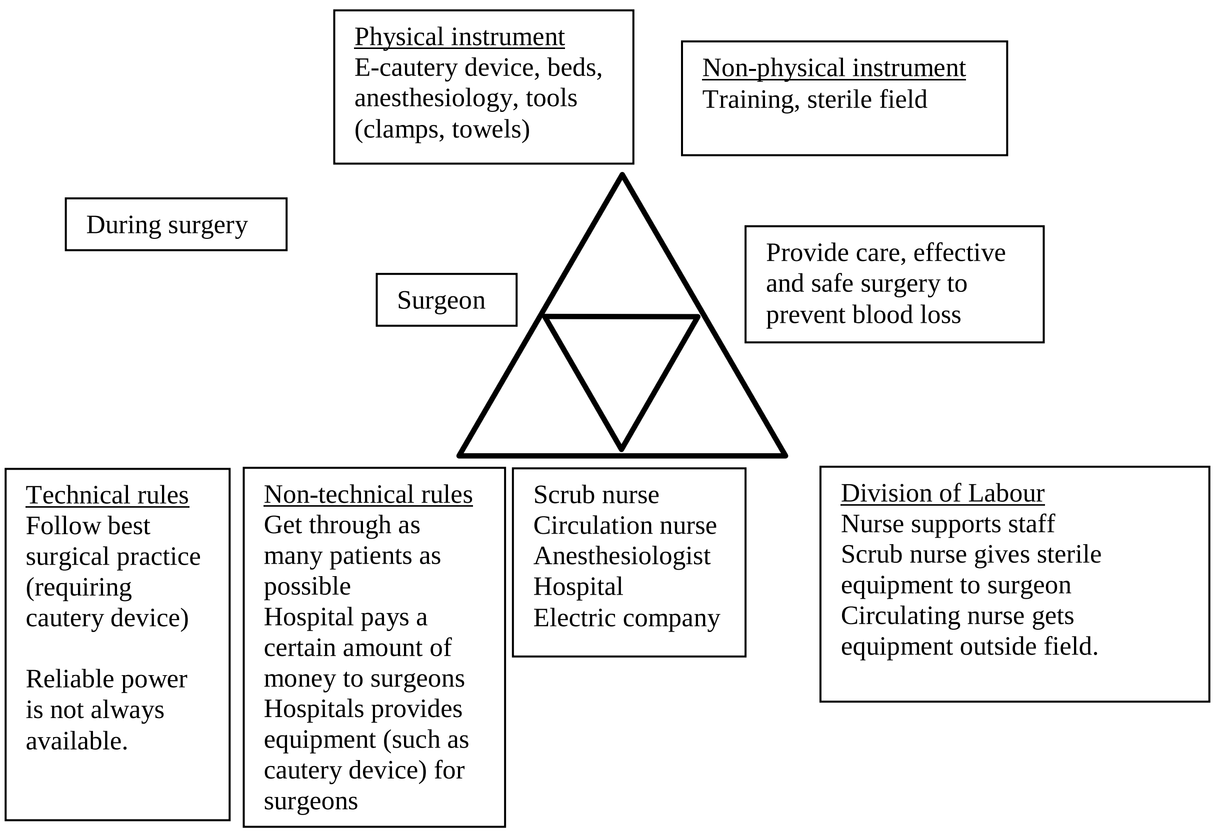

Figure 6-5 Activity System 1 for Focus Group 3

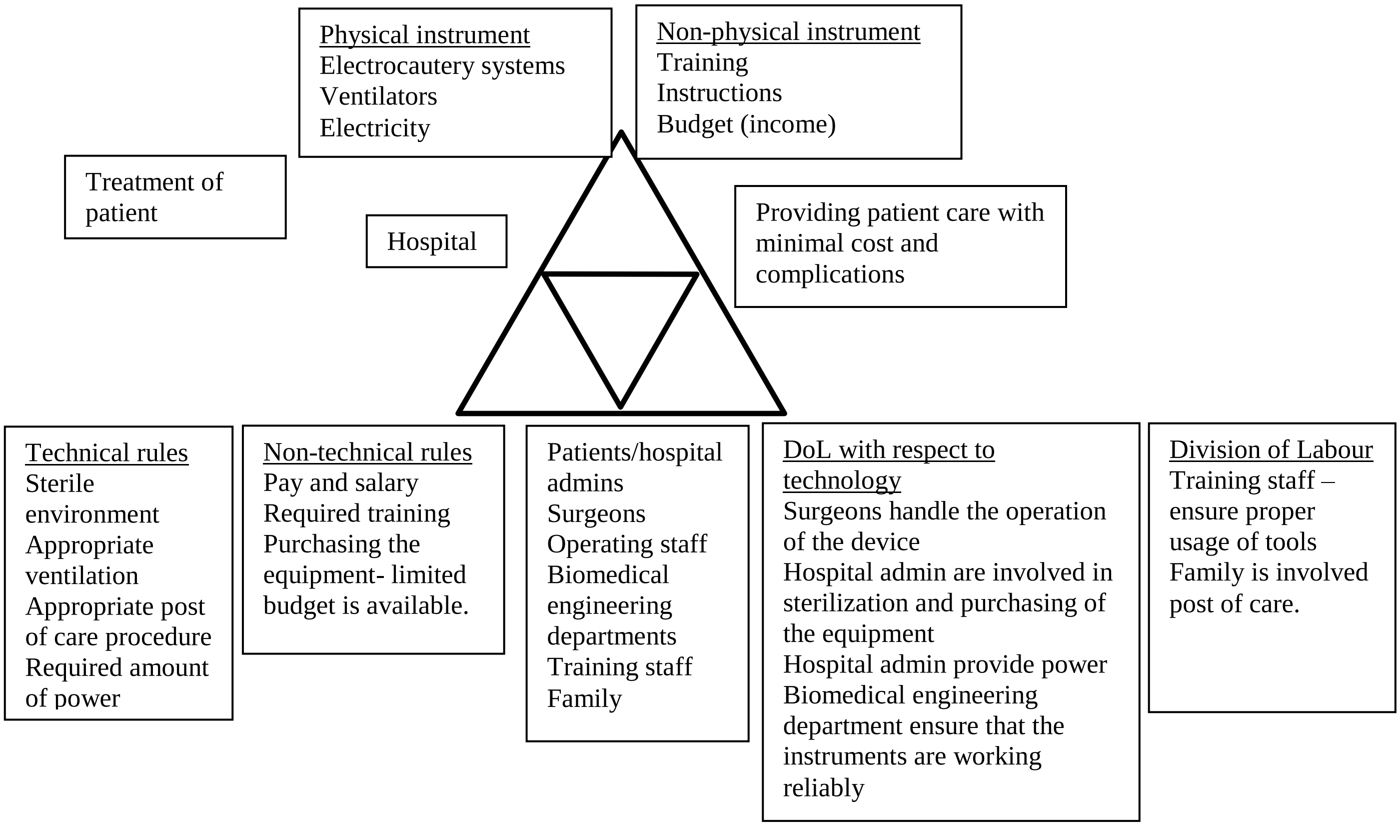

Figure 6-6 Activity System 2 for Focus Group 3

Identify Contradictions

- Contradiction between non-technical rules in AS 2 and non-technical rules in AS1 - Hospital has limited budget and cannot provide instruments
- Contradiction between technical rules in AS 1 and in non-technical rules in AS2- No cautery tool is available and cautery is essential for good medical practice
- Contradictions between instrument in AS 1 and the technical rules in AS1- Hospital cannot provide reliable power but power is needed for use of instruments
-

Develop Need Statement

Desired change: to provide reliable electro-surgery – blood clotting and tissue clotting
Metrics: amount of blood loss – number of procedures with electro-surgery
Statement: a method to reliably cut and cauterize tissues even of the event of power outages to reduce blood loss during the operation

Reflection - Potential improvements:

- Sterile field is better fit as part of the technical rules.
- Both are missing outcome.

- Hospital is too generic and it would be better if it was a specific group within the hospital, for example the procurement staff or the biomedical engineering group.
- The activity system do not reference the clinical challenge – part of that is choice of the activity, part of it is lack of detail in the AS.
-

Reflection - Current application

- The scope of analysis is appropriate for AS 1 with the local surgeon. All the elements can be assessed in much more detail compared to AS 2.
- What is a technical/non-technical rule? What is DoL/DoL with respect to technology? What is physical/non-physical instrument? What is an outcome vs. objective? How do I define these after I see these applications?

A.6 Focus group 3 – Biodesign

Table 6-3 Biodesign Steps for Focus Group 3

Stakeholder analysis	State observations	State problem statements
Patient Nurse Primary care doctor Surgeon/specialist Family Scrub nurse Hospital Insurance provider Manufacturer Engineering team Distributor	Cycle care Urinary tract symptoms Referral process Diagnosis Treatment Post operation Large number of procedures in a day Low cost solution High temperature light source Need for a mobile solution High power consumption Family take off work to care for patient Discomfort with different gender doctors Unreliable electricity supply No diagnosis – acute symptoms presented Lack if repair and maintenance Limited budget Public system has low paying capability Big market Limited electricity (power outage) Limited budget Nurse training, availability and ability to recognize need for referral In the referral process there are red tapes and long waits for physicians Family needs to take off work to drive patient	Power goes out or power surges Procedure is delayed

Need statement

A system to reliably see inside the UT to increase the number of diagnosis of urinary diseases for female patients in low resource setting

A.7 Focus group 4 – ATNF

Stakeholder Analysis and Identify Activity

- Many charities from Canada
  - Accepting donation
  - Shipment
  - Follow-up
- Recipient government
  - Distribution
  - Sometimes verifying standards
  - Pay for shipment
- Recipient hospitals
  - Training
  - Receiving
- Recipient organization
  - Evaluate equipment
  - Distribute
- Physician from Canada
  - Donate their own equipment
  - Raise awareness
- Canadian hospitals
  - Donate their own equipment
  - Raise awareness
- Biomedical engineers
  - Checking standards of equipment
  - Fixing equipment
  - Training healthcare worker to use and maintain equipment correctly

Identify two key activities

- Donation of equipment
- Distribution of donated equipment

Construct Activity Systems

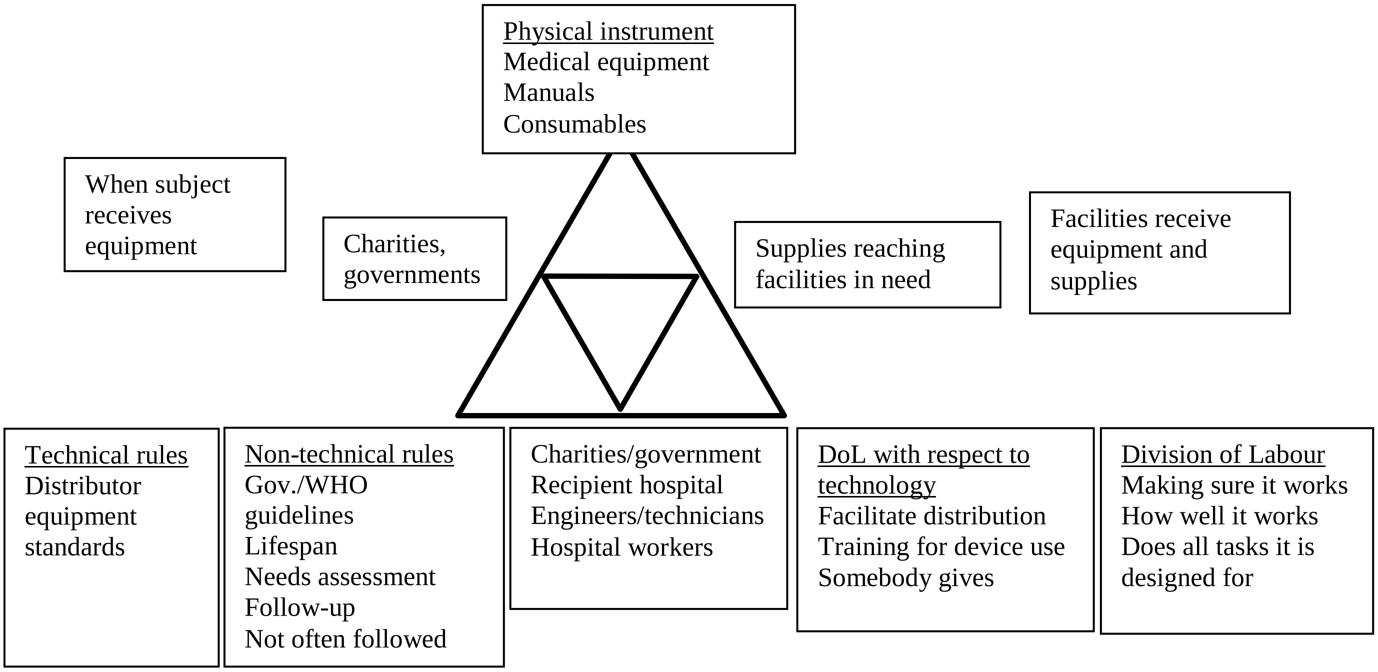

Figure 6-8 Activity System 1 for Focus Group 4

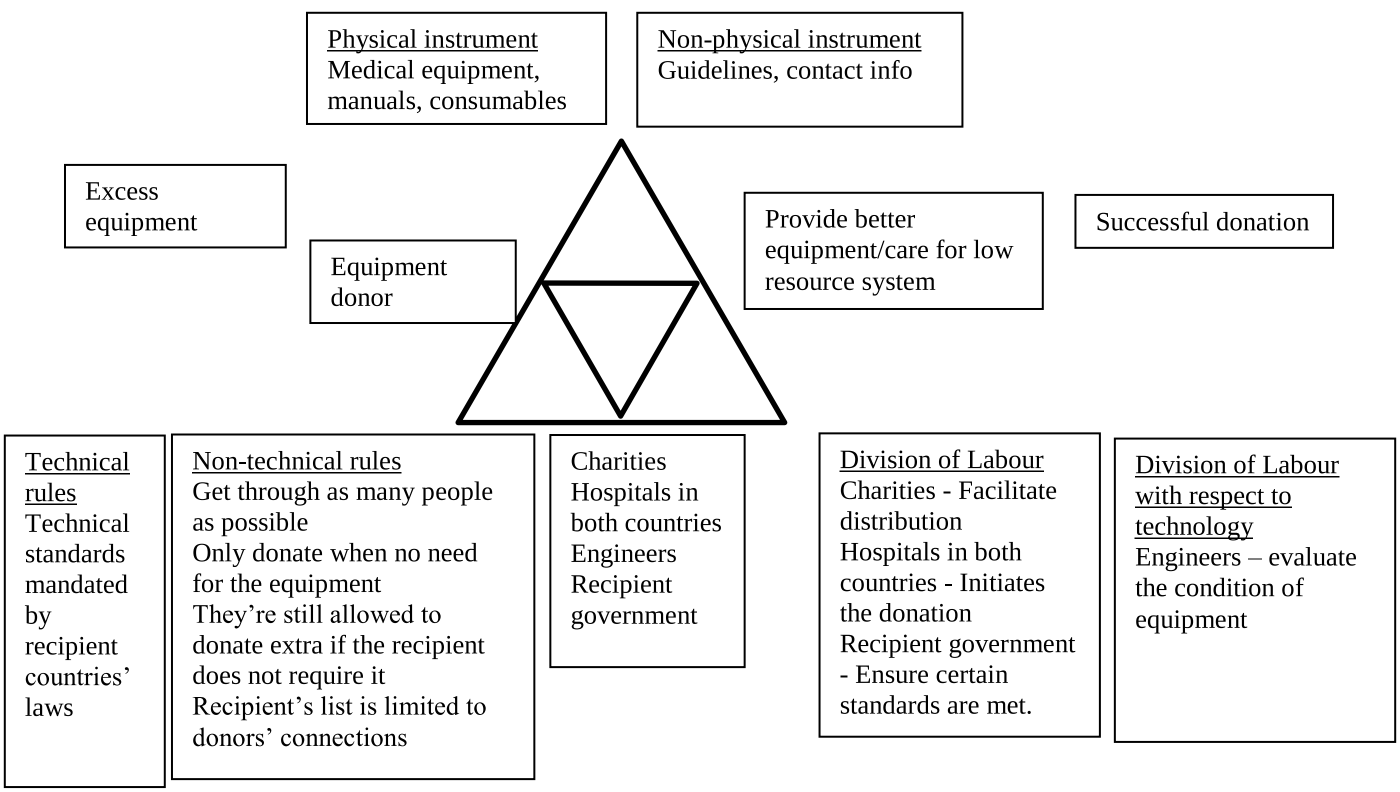

Figure 6-7 Activity System 2 for Focus Group 4

Identify Contradictions

- People donating do not necessarily know what the receiving organization need and are not connected to them.
- The equipment that are received are not matching the needs of the receiving context and eventually do not get used because they are not compatible with that environment.

Develop Need Statement

A method to increase the efficiency of the donation system by more effectively matching donors with recipients through distributors, and by increasing the percentage of successful and high-quality donations.

A.8 Focus group 4 – Biodesign

Table 6-4 Biodesign Steps for Focus Group 4

Stakeholder analysis	**State observations**	**State problem statements**
Patients Friends and family Hospital admin Public and government care system Physician Nurses Public/gov. care system Local members with no/minimal training Cycle care Femur fracture → patient, friends and family → care facility, hospital admin → nurses, local members with minimal or no training, doctors, surgeons → rehab facilities → friends and family Flow of money Patients → friends and family → hospital → suppliers Public/gov. care system → doctors, surgeons, nurses, hospital admin Donated pins/ donors	State observations Patient missing work (no money) It is difficult for patient to get to hospital No proper sterilization method for open wound caused by the pin Patient develops pressure sores over time Patient immobility causes muscle fatigue No first response system/care Patient misses 3 months of work Takes time to even get to hospital in the first place May live far away, won't come back for post treatment check-up Patients don't come back for rehab/physio after the treatment There is a long wait list/ wait time before the patient gets treated Traction devices are not proper surgical/medical supplies Autoclaves are not always working Motorcycle incidents cause most femur fractures → maybe the traction problem can be greatly alleviated by tackling this at root cause. How do you diminish number of accidents? Takes long time for patient to get to hospital Not enough trained hospital staff Not enough hospital resources e.g. bandages Surgery has negative stigma High infection rates Patient misses 4 months of work Patient in bed for 4 months Patients live far away from the hospitals Often surgeons/doctors aren't the ones performing traction Immobility of patient for 3 months is a problem Admission to hospital is time consuming, poor system Lack of treatment because sometimes patient have a tough time going to hospitals Missing work for 3-4 months Lack of rehab at times Why all the infection? If we could avoid traction all together, that could be beneficial When patient is in the hospital for long duration, patient loses income which makes them less likely to seek out treatment for future health problems 4 months is a long time so the hospital, employers, patients, etc. are all strongly impacted by it.	Road/traffic system First response system → lack of transport to hospital Wait time at hospital to get treatment (administrative issue) Sterilization of equipment (autoclaves may not work) Lack of training for people actually performing treatment Material used for traction care not proper medical equipment → not proper method for applying weight Immobility → pressure sores, muscle fatigue, etc. Pin infection → open would for long periods of time

State Need Statements

A method to improve traction treatment in low-resource system to reduce hospital stay time and better bone union in a larger percentage of patients.

A.9 Focus group 5 –ATNF

Stakeholder Analysis and Identify Activity

- Child
  - Child is being monitored for vital signs
- Family
  - Family alerts nurse/doctor when child is in distress
- Doctor
- Nurses
  - Are monitoring the patient
    - Nurses are checking and recording the patient's respiratory rate
    - Nurses are responding to patients in distress (bot breathing)
- Engineers
  - Fix broken equipment
- Hospital procurement
- Hospital management
  - Hospital finances wards
  - Equips wards with equipment
  - Hospital pays doctors and nurses
- Non-governmental organizations
- Donors
- Government

Construct Activity Systems

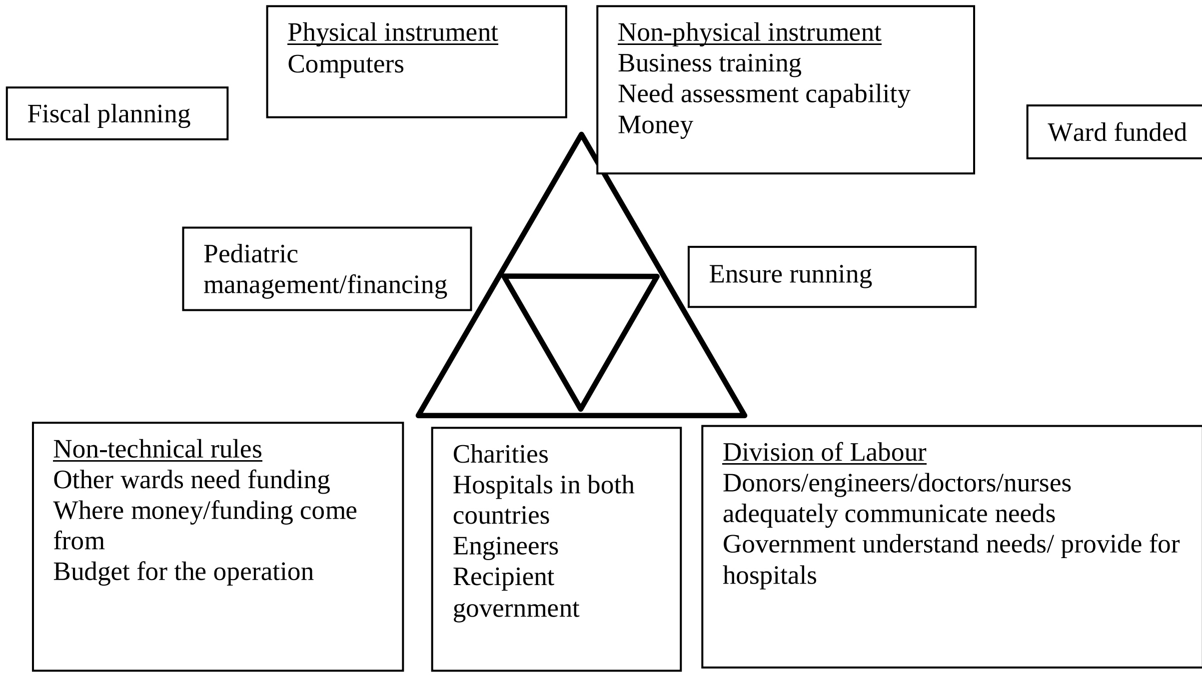

Figure 6-9 Activity System 1 for Focus Group 5

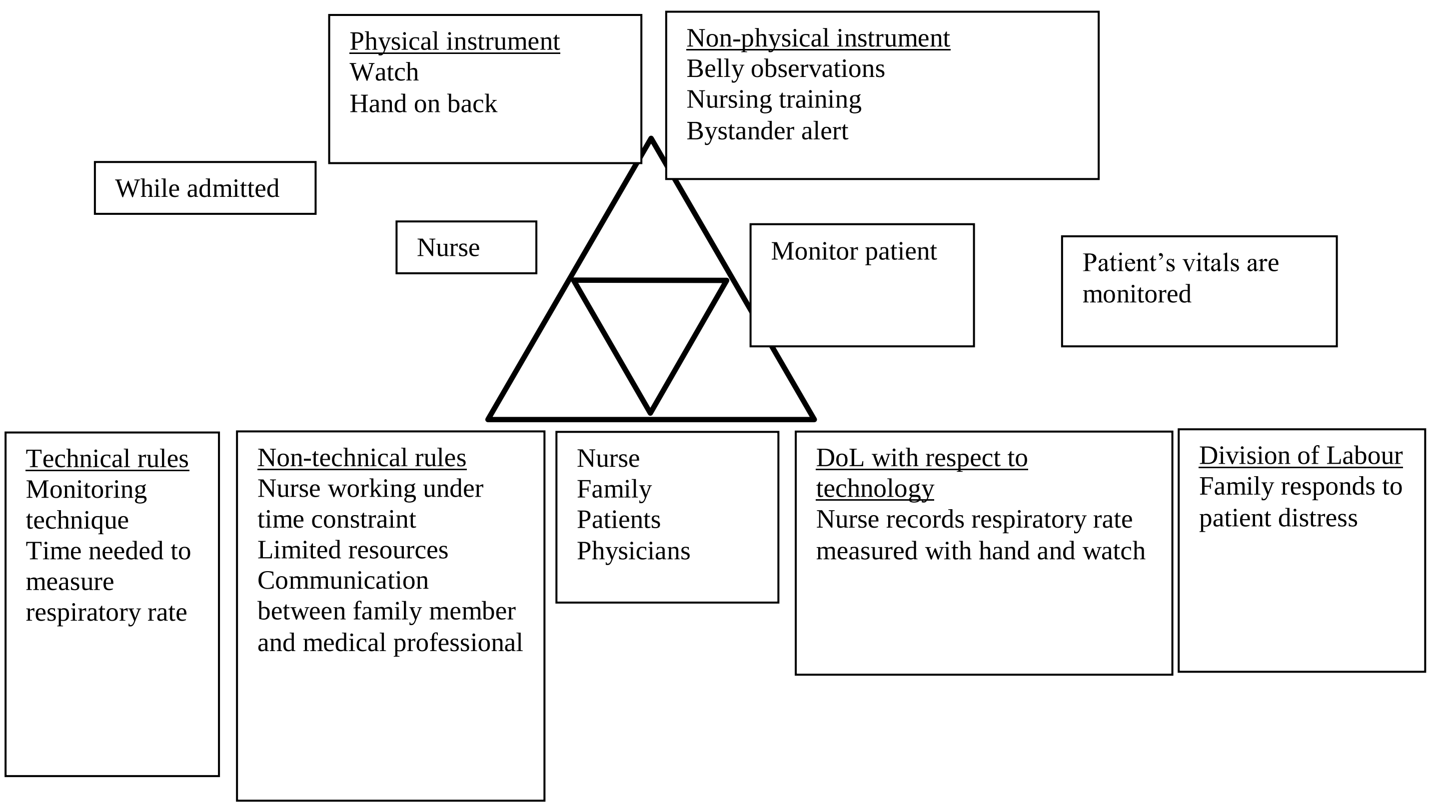

Figure 6-10 Activity System 2 for Focus Group 5

Identify Contradictions

- Nurse needs certain amount of time to monitor but they are under time constraint
- There are competing groups for funding in hospital
- The resources needed by nurse for the monitoring activity are greater than the amount provided
- The fiscal planning is only at one point in time, while monitoring is continuous. It is hard to predict the amount of resources required.

Develop Need Statement

A low cost method to ensure and expedite occurrence of respiratory rate monitoring and improve respiratory distress detection for paediatric patients with respiratory conditions in low resource settings.

A.10 Focus group 5 – Biodesign

Table 6-5 Biodesign Steps for Focus Group 5

Stakeholder analysis	State observations	State problem statements
Baby/family Doctor Nurses Engineers Lab technician Hospital procurement Hospital management Non-governmental organization Donors Governments	Baby is treated Baby's family relies on hospital / device for treatment Nurse interacts with device the most Nurse is most likely the most hands on with the device Technician/nurse replaces bulb Nurse/doctor encounters problem with device needs it quickly fixed Lots of management people who are worried about money Engineers maintain and fix device Engineer troubleshoot device and collects data Engineers test the device Engineers may sometimes not be actual engineers – maybe more of a mechanic/technician Lab techs evaluate care/treatment Procurement funds/acquires device Doctors purchase device Doctors need to see value in device to buy it themselves or ask hospital to buy it Donors could donate money for device or the device NGO's could facilitate donations Federal government funds hospital Nurse are busy and don't have a lot of time per patient Nurse could misread the device	Resource and financial tool on family, hospital and other patients Technical (to do with device failure) Human error (reading device wrongly) Errors in fixing and maintaining the device Bureaucratic issues Marketing (not interested/ don't see devices worth) Education about device Economic problems (can't afford to keep changing bulbs) Adverse effects on patient Legal problems (device doesn't work – unhappy patient)

Need statement

- Target audient: baby/patient with jaundice in a low resource setting
- Desired change: improved treatment process
- Metric: ensure safe duration and treatment, adverse effects – skin damage
- Statement: a method to improve jaundice treatment process for newborn babies in low resource settings by ensuring proper treatment duration and minimizing adverse effects

A.11 Focus group 6 – ATNF

Stakeholder Analysis and Identify Activity

- ICCHANGE
  - Communication with hospital
  - Data analysis
  - Project management
- Doctors/surgeons → patient diagnosis
- Patients
  - Recording patient data on paper surgery
  - Come to trauma unit hospital for treatment
- Nurses → patient care/patient intake, record some data
- Hospital admin → organizes patient records, makes decisions for hospital
- Government → Funding, ensure general well-being of citizens, regulations

Construct Activity Systems

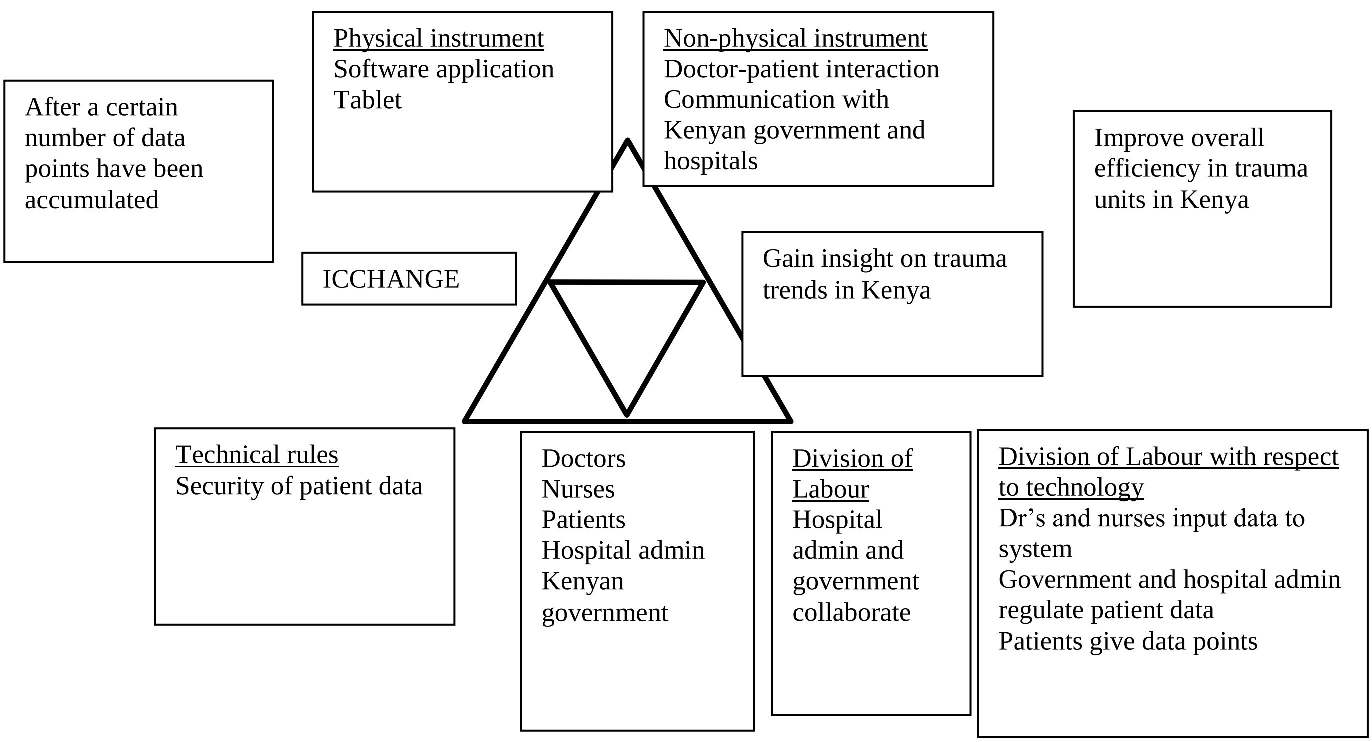

Figure 6-11 Activity System 1 for Focus Group 6

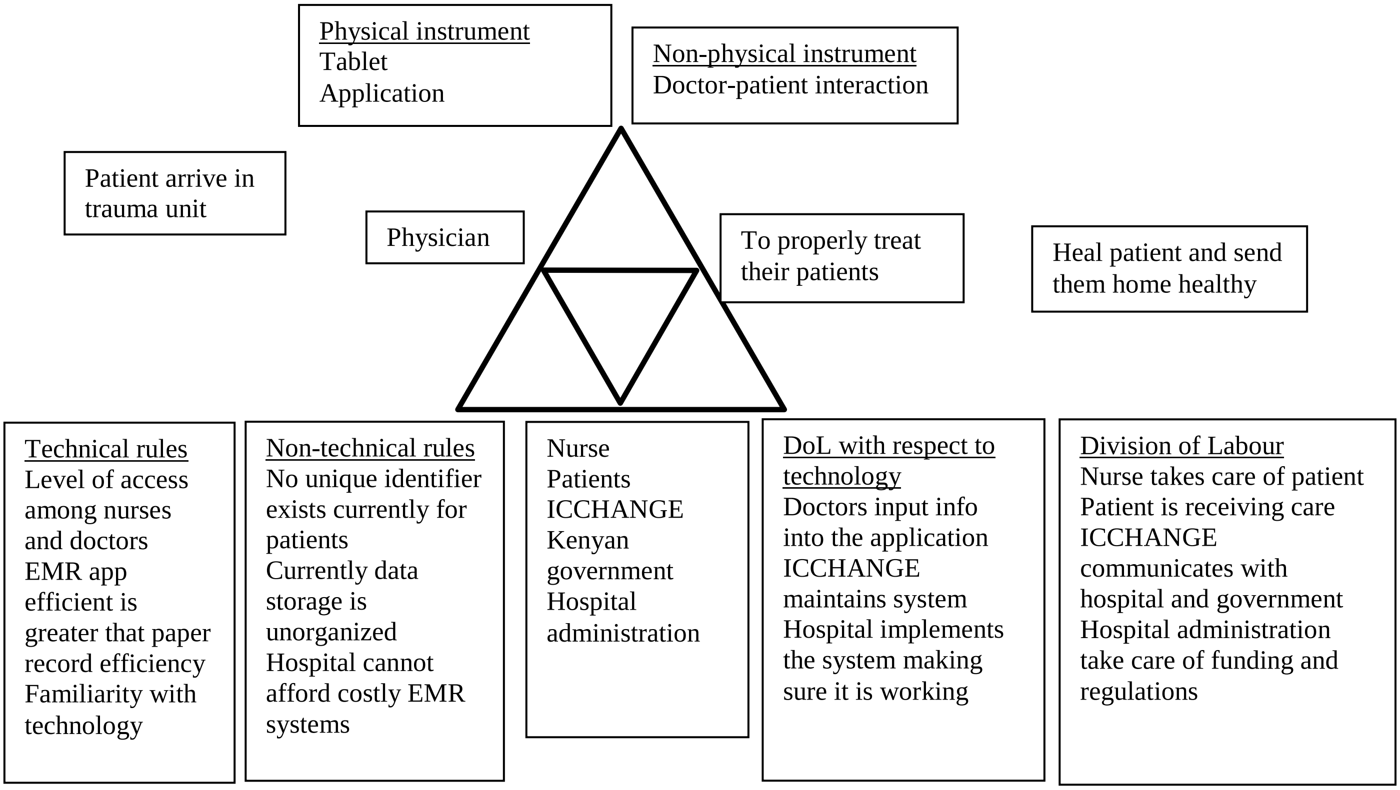

Figure 6-12 Activity System 2 for Focus Group 6

Identify Contradictions

- Patient privacy versus access to data
- Ease of use versus maintaining organization
- Funding for tablets versus implementing the technology

Identify Need Statement

A method to increase efficiency in trauma units so that they can provide improve patient care in Kenyan hospitals as indicated by satisfaction of doctors and nurses and overall cost of implementation

A.12 Focus group 6 – Biodesign

Table 6-6 Biodesign Steps for Focus Group 6

Stakeholder analysis	State observations	State problem statements
Future investor Stroke patient Musical therapist Physiotherapist BEST team Future investors	Some things not technically possible Emotions are at stake Most patients are old Musical therapist would own the device Musical therapists are not technically competent – they have unrealistic expectations Patient has stroke, they visit therapist and they interact with device The goal is to integrate physical and musical therapy Extensive physiotherapy required to gain full functionality Physiotherapy exercises are boring Squeeze, tap and twist are some of the functions that they are considering.	Extensive physiotherapy required to gain full functionality Physiotherapy exercises are boring

State Need Statements

A method to improve emotional response to physical therapy for stroke patients facilitated by musical therapist so that patients adhere to their prescribed therapy

A.13 Focus group 7 – ATNF

Stakeholder Analysis and Identify Activity

- Technicians
  - Maintaining device and performing repairs
- Newborns
  - Being place under lamp (receiving blue light therapy)
  - Device directly affects them
- Doctor/nurses
  - Monitoring the patients and the equipment involved their core
- Parents
  - Emotional and financial support
  - Monitoring the patient
- Biomedical engineers
  - Designing the device (PTM)
- UBC BEST – board of directors
  - Sponsoring the project/organizing team
  - Advising the project
  - Supervises monitor (working or not)
  - Contact others if need
- Hospitals
  - Ensuring proper health
- Regulatory bodies
  - Device passes standard safety measures
- Potential investors
  - Identify opportunities to invest money
  - Provide funding to manufacture the device
- Manufacturers
  - Build, assemble and test the device

Construct Activity Systems

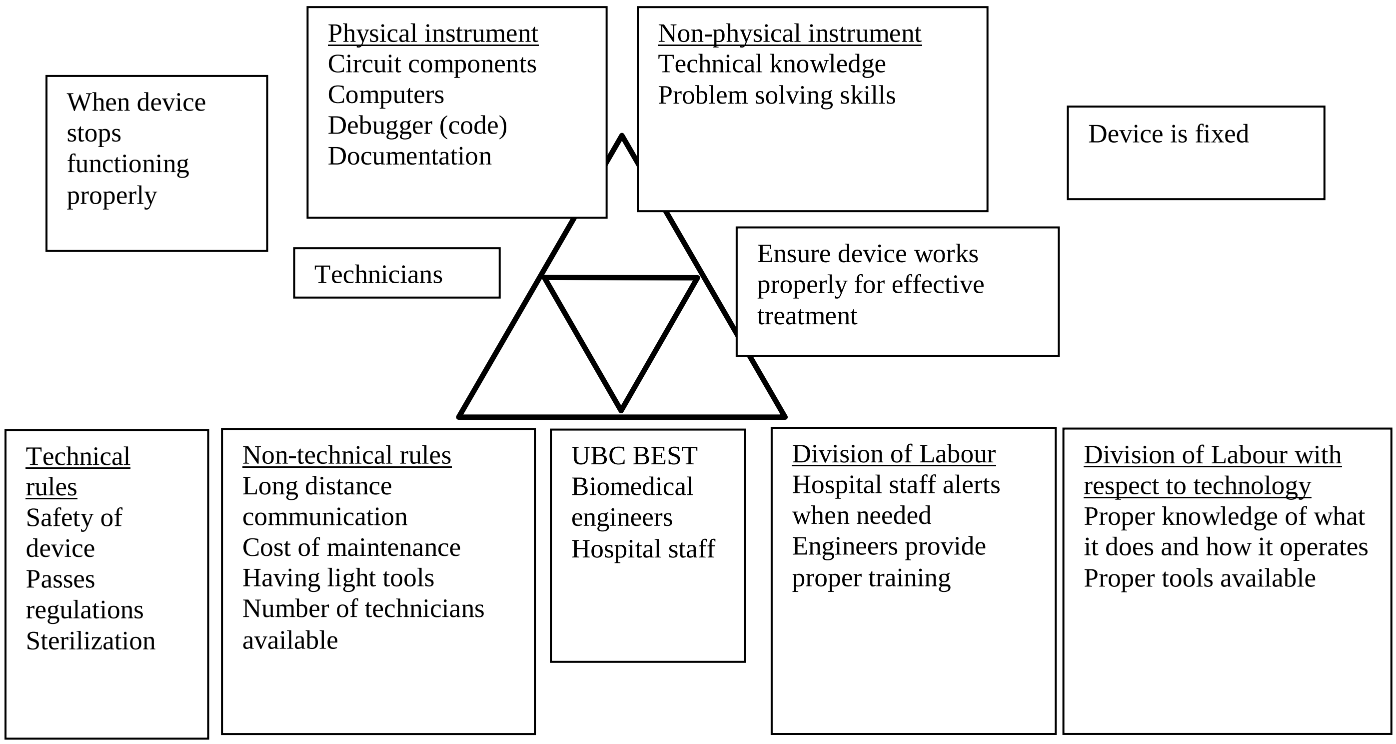

Figure 6-13 Activity System 1 for Focus Group 7

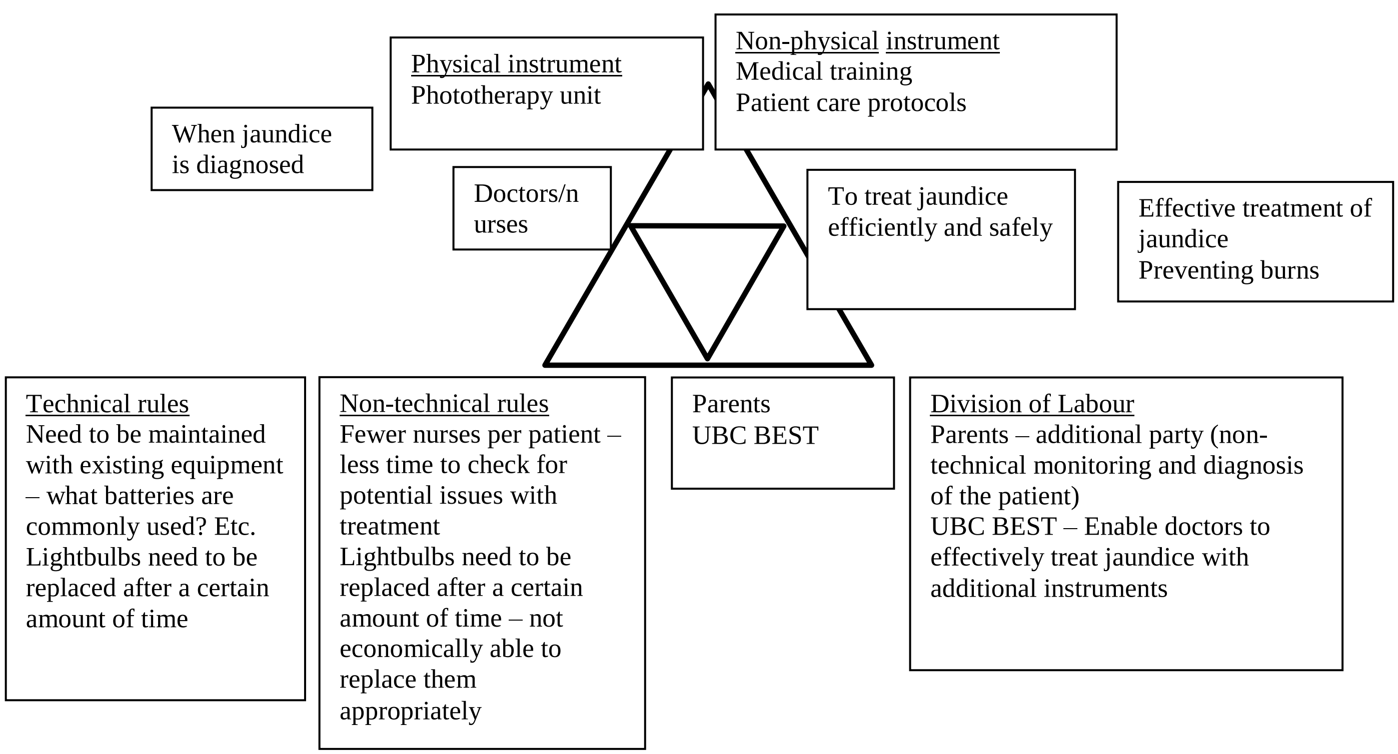

Figure 6-14 Activity System 2 for Focus Group 7

Identify Contradictions

- If phototherapy monitor says replace light, the ward might not have more lights, then the monitor becomes a useless device
- Lack of hospital staff – will checking this device take time away from other patients
- Keeping maintenance cost low when other tools are needed to fix the device

Identify Need Statement

A method to improve the treatment of jaundice by using minimal resources (costs, staff, time) for hospital staff in low resource countries so that treatment time is reduced.

A.14 Focus Group 7 – Biodesign

Table 6-7 Biodesign Steps for Focus Group 7

Stakeholder analysis	**State observations**	**State problem statements**
Doctors - Doctors are involved when the device gives an alert on a medical emergency Nurses - Nurse observe respiratory rate and check on patients - Directly responsible for monitoring patient. Limited resources Children - Less active - Prone to respiratory problems - Can (maybe) communicate pain or discomfort before they stop breathing Parents - Observe whether they are breathing (extra source of respiratory monitoring) NGOs - Provide connection to hospital staff Manufacturers Hospital equipment department Investors - Provide funding	Some funding available for device purchases Existing equipment is expensive and difficult to maintain given the setting (low resource) Malfunction of recognition (monitoring) can affect time to respond Can worsen existing implications Takes away time from nurses	Takes away time from nurses Existing equipment is expensive and difficult to maintain given the setting (low resource) Malfunction of recognition (monitoring) can affect time to respond

State Need Statements

A method to continuously monitor respiratory rate in children for hospital staff (nurses) in Ugandan hospital so that they can take action when necessary, which will reduce time observing patients and allow more time to treat patients.

Appendix B Ethics application, consent forms, workshop outline and questionnaire

B.1 Letter of Initial Contact

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Letter of Initial Contact:
Need Finding Technique based on Activity Theory

Principal Investigator:
H.F. Machiel Van der Loos, PhD, P.Eng.
Associate Professor
Dept. of Mechanical Engineering
University of British Columbia

Co-Investigator:
Shalaleh Rismani, M.A.Sc. Candidate
Design Researcher
Dept. of Mechanical Engineering,
University of British Columbia

Dear __________,

As a student, instructor or mentor of the Engineers in Scrubs program, the New Venture Design course, CPSC 444, the Biomedical Engineering Student Team, and other design based coursed at University of British Columbia we are asking you to participate in a study examining design need-finding strategies that can be used to collaboratively innovate medical technology.

The purpose of this study is to examine the experiences of the student design teams as they are going through a needs assessment phase and to test various design methods of need-finding that can lead to more comprehensive list of design needs of new medical devices. The research will explore how using these strategies could improve the capacity for innovative ideas and identifying latent needs for various clients in the medical device domain.

The research will be qualitative in nature, focusing on the design student team's experiences. The research team will facilitate focus group discussions and interviews with participants about their experiences and seek new ways to look at process of need-finding. The research team will also observe participants during these focus group session to gain an understanding of the interactions within each team when developing needs for a medical device. The researchers may also follow up with the teams, instructors and mentors after the workshop if there is interest to discuss the process and outcomes.

The information gained from this research may appear in various publications, reports and/or conference proceedings. All study participants will remain anonymous and any details related to the projects will be disguised. As a study participant, you may request copies of these publications.

If you do not wish to participate in the study, please let us know and we will ensure that your wishes are respected.

Please contact Shalaleh Rismani to request additional information. Your time and interest in this study are much appreciated. On behalf of the research team,

Dr. H.F.M. Van der Loos

Design Innovation / Version: January 26, 2016 Page 1 of 1

B.2 Consent form and demographics form

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Consent Form
Need Finding Technique based on Activity Theory Sub-study

Principal Investigator:
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Associate Professor
Dept. of Mechanical Engineering
University of British Columbia

Co-Investigator:
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Co-Investigator:
Dr. Piotr Blachut, MD, FRCSC
Orthopaedic Surgeon
Department of Orthopaedics
University of British Columbia

Co-Investigator:
Florin Gheorghe, M.A.Sc. Candidate
Design Researcher
Dept. of Mechanical Engineering,
University of British Columbia

Purpose:
The purpose of this study is to examine the experiences of student design teams as they are going through their project's needs assessment phase and to test various design methods of need-finding that can lead to better formulations of design needs of new devices. The research will explore how using these strategies could improve the capacity for innovative ideas and identifying latent needs for various clients in the domain of medical and personal-use device. This sub-study is part of the M.A.Sc. thesis of Shalaleh Rismani, who is the only co-investigator that is currently involved with this sub-study.

Study Procedures:
The research will be qualitative in nature, focusing on the student design teams that are currently enrolled in the Engineers-in-Scrubs program, the New Venture Design course, CPSC 444, and other design based courses at University of British Columbia. In addition, members of the Biomedical Engineering Student Team are invited to participate in the study as well.

The research team will conduct one semi-structured focus group, which is aimed at testing various design strategies and will take no longer than two hours. Audio, photo, and video recording may take place. The focus group will be followed by a reflective questionnaire for the participants which will take no longer than 15 minutes.

After the focus group, the research team will present the results of the focus group discussions to the course instructors, teaching assistants and mentors in form of a "need statement evaluation" questionnaire.

The research team may interview design team members, course instructors, teaching assistants and mentors individually to discuss the results and methods used in the focus group. The interviews will not take more than thirty minutes. This is an optional secondary engagement and would explore the same questions as the focus group in further detail. Recording of sessions may take place.

Potential Risks:
The physical, emotional or psychological risks associated with this sub-study are minimal. The participants will only participate in a facilitated need finding workshop and will be asked questions about their project.

Potential Benefits:

Participants could benefit from learning about design strategies to increase their capacity for expressing innovative ideas and approaches in their work. An indirect benefit is that the outcomes of this research will inform the development of innovative technology.

Confidentiality:
All data will be kept in a locked cabinet, and computer files password protected. Participants will not be identified by name in any reports of the completed study; only the research team will have access to this information. Participants are able to seek attribution if they wish to do so. The research team will ensure to protect the privacy of the participants; however, it is important to acknowledge that the ability to guarantee confidentiality in a focus group is limited.

Contact for information about the study:
If you have any questions or desire further information with respect to this study, you may contact Shalaleh Rismani.

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without jeopardy to your work or participation in any future design oriented activities. The decision to participate or not to participate will have no impact on your academic program.

Initial here if you are providing consent for interview/focus group discussion ___________

Initial here if you are providing consent for photography / audio / video (circle one or all) recording:

____

Your signature below indicates that you have received a copy of this consent form for your own records.
Your signature indicates that you consent to participate in this study.

____

Subject Name (print) Signature

____

Date

In addition and separately, I agree to allow my comments to be quoted in reports or publications. If a quote were used, there would be nothing in the quote that could identify me, or any of my clients.

____

Subject Name (print) Signature

_______________ Date

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Demographics Questionnaire
Need Finding Technique based on Activity Theory Sub-study

Principal Investigator:
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Co-Investigator:
Shalaleh Rismani, M.A.Sc. Candidate
Design Researcher
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1. What is your gender?

- ☐ Male
- ☐ Female
- ☐ Not disclosed

2. What is your age?

- ☐ 18-24
- ☐ 25-34
- ☐ 35-44
- ☐ 45-54
- ☐ 55-64
- ☐ 65+
- ☐ Not disclosed

3. I am a/an?

- ☐ Student
- ☐ Instructor
- ☐ Mentor
- ☐ Other ________________

4. What is your academic background?

5. How would you describe your expertise in design projects?

B.3 Observations and Focus Group Protocol

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Focus Group Protocol
Need Finding Technique based on Activity Theory Sub-study

Consent Process
Thank you for reading and signing the Human Subjects Consent Form for this project entitled "Need Finding Technique Based on Activity Theory Sub-study".

Completion of the Questionnaire
Before we start, please take a few minutes to complete the "Demographics Questionnaire" we are handing out now. The answers to these questions will help us to provide a very basic description of this group when we write up the results. No information that identifies you personally will be reported, only the collated results from the group.

Introduction
Thank you for agreeing to take part in this study. My name is ___________________________ and I will be facilitating today's group discussion. I am a research assistant working with Dr. Mike Van der Loos, who is an Associate Professor in the Department of Mechanical Engineering of the Faculty of Applied Science at the University of British Columbia.

We have invited you to take part in this workshop today because you are currently enrolled in the Engineers-in-Scrubs program or New Venture Design Course. This sub-study is about understanding how engineers and designers use different tools to identify needs specific to a certain problem space. This sub-study is part of a larger study on design innovation for development of medical technologies in the context of international surgery.

Today I am playing two roles: that of a facilitator and that of a researcher. This means that I will facilitate this workshop, while at the same time I am trying to test and evaluate the design process itself.
At this time I would like to give a brief overview of the project. [5min]

Why – The background and motivation for this project [2 min]

How – A brief summary of how the research team will undertake this project (phases, persons involved, project timeline) [3 minutes]

Ground Rules of Discussion

I am going to facilitate your group through 2 different need-finding activities. A framework will be provided for these activities. There is not a particular way to engage with these activities but we do want everyone to take part in the discussion as your ideas are all important to our research.

This workshop will include a lot of team discussion. Feel free to treat this as a discussion and respond to what others are saying, whether you agree or disagree. We're interested in how you engage in these activities based on your own understanding of the instructions. There is no right or wrong answer. We are here to learn from you.

Please do respect each other's answers and opinions during the workshop. We ask that only one person speak at a time.

We will treat your team discussion in the workshop as confidential. We are not going to ask for anything that could identify you and we are only going to use first names during the workshop. We also ask that each of you respect the privacy of everyone in the room and not share or repeat what is said here in any way that could identify anyone in the room.

We are video and audio-recording the workshop today and also taking notes because we don't want to miss any of your comments. Once we start the video and tape recorder, we will not use anyone's full name and we ask that you do the same.

We will not include your names or any other information that could identify you in any reports that we write. We will destroy the notes, videotapes and audiotapes after we complete our study and publish results.

Finally, this workshop is going to take about 2 hours. You are free to leave at any time, though we would prefer if you stay for the whole time.

Does anyone have any questions before we start?
[Start tape and video recorder]

Instructions for Focus Group Participants:

You will be asked to complete two need finding exercises on your course project. The first need finding exercise is a conventional need finding practice that is mainly based of the Stanford Biodesign Process. The second need finding exercise is developed throughout this research and it specifically incorporates Activity Theory. Please feel free to use the necessary whiteboard space and necessary tools to complete the tasks.

Definition of terms:

Observations – The data and information that the design team gathers from their research
Stakeholder – All the individuals and organizations involved with the project
Problem statement – Inadequacies or limitations derived from observations on the project
Need statement – A statement that identifies a necessary change and it includes a metric
Activity Theory – Cultural-historical psychology theory describing the relationship between humans and the tools they use to reach their objectives
Activity system – A triangular framework that connects the elements of an activity – subject, object, instrument, community, rules and division of labour.
Contradictions – Inconsistencies and tension points in an activity system or between activity systems
Need finding – The process of defining needs in a product development firm

Part A: Conventional Need Finding (45 min)

In this section you will be asked to complete a conventional need finding exercise.

Task 1: Identify main stakeholders

Based on your research and experience with your project so far identify the main stakeholders. Briefly describe the role of each stakeholder.

Task 2: Discuss observations and problems

Highlight some of the key observations that you have had so far in the project. What has stood out to you as you have talked to your clients? What are some of the insights that you have had with regards to your project? What are the problems that you see associated with your observations? Why do they exist? Write a few critical problem statements that correspond to your observations.

Task 3: Write need statements

Based on the observations and problems you noted develop need statements. Make sure to associate a need statement with a problem statement and an observation. Write a need statement that is verifiable and has a specific scope. The need statement should identify a change and have a few key metrics.

Part B: Activity Theory Based Need Finding (45 min)

In this section you will be asked to complete a need finding exercise based on Activity Theory.

Task 1: Identifying activity systems

From your stakeholder analysis pick 2-3 major activity systems that you would like to analyze in this activity. Define the activity systems by defining the following: subject (i.e. your stakeholder), object, outcome and time of the activity. Refer to the activity system hand-out for the definition of each one of these terms.

Task 2: Developing activity systems

Based on the questions in the activity system hand-out define the three activity systems in full detail. Write out the answers to these questions in full and concise sentences in the appropriate section.

Task 3: Identifying contradictions

Now that you have your activity systems identify contradictions within or between the three activities. Describe the contradictions using the following format:

Type of contradiction (i.e. between two elements of one activity, between elements of two activities)	
The contradicting elements	
Description (**What** is the contradiction? **Where/when** is it taking place? **Why** does it exist? **How** can it be resolved?)	

Task 4: Developing need statements from contradictions

The final task is to convert your contradictions to need statements using the following the questions:

1. Identify what needs to be changed for the contradiction to be resolved.
2. Identify a few key metrics based on the activity network for that change.
3. Write a need statement that is verifiable and has a specific scope. The need statement should identify a desired change and have a few key metrics.

Thank you very much for your time and for sharing your opinions with us. I would really appreciate it if you could take few minutes to complete this questionnaire about your experience in the workshop.

We look forward to coming back to share with you the results of this study. Do you have any advice for us before we conclude for today?

Protocol for Observation of the Focus Group

The facilitator will also play the role of an observer when the student teams are using the need finding techniques.

The intended goals for observation are:

- To gain insights on challenges faced by the teams when they are using they two techniques
- To conduct an ethnographic analysis of use of these two techniques

The facilitator will specifically be looking at the following aspects of need finding phase throughout the observation period:

- What are the roles and interactions of various team members?
- How much time do the teams spend on the various parts of each task?
- What difficulties, constraints, and challenges arise as a result of use of the two techniques?
- What adaptations and moment-to-moment improvisations in practice are the design teams making in order to adapt to the challenges?

The observing researcher will not be collecting any identifying information about the procedure aside from a general explanation of what type of procedure is being performed/. No identifying information will be collected on any of the participants under the observation.

All the participants will be asked to sign a consent form for observation.

ACTIVITY SYSTEM

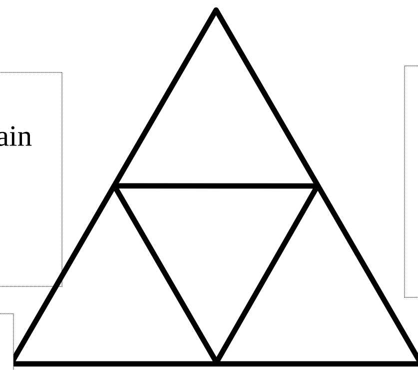
TIME
When is this activity taking place?

NON- PHYSICAL INSTRUMENT
What are the non-physical tools that facilitate the connection between the subject and the object?

PHYSICAL INSTRUMENT
What are the physical tools that facilitate the connection between the subject and the object?

OUTCOME
What has been changed through this activity? What is the end result of this activity?

SUBJECT
Who is the main actor of this activity?



OBJECTIVE
What is the main motivation of the subject for this activity?

NON-TECHNICAL RULES
What are the social, economic and political constraints and conditions that govern the relationship between subject, community and object?

TECHNICAL RULES
What are the technical requirements that need to be addressed considering the relationship between subject, instrument and object?
What is the manufacturing landscape like for the specific technology?
What are the appropriate clinical regulatory procedure?

COMMUNITY
Who are the organizations and individuals that help the subject achieve their objective?

DIVISION OF LABOUR
What is the role of the community members when it comes to helping the subject achieve the objective of this activity?

DIVISION OF LABOUR WITH RESPECT TO THE TECHNOLOGY
What is the role of the subject and the community in development, use and maintenance of the technology used in this activity?

B.4 Post-workshop questionnaire

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Workshop Questionnaire
Need Finding Technique Based on Activity Theory Sub-study

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Co-Investigator:
Shalaleh Rismani, M.A.Sc. Candidate
Design Researcher
Dept. of Mechanical Engineering,
University of British Columbia

The questionnaire is about your experience with the use of two different need finding methods: conventional need finding versus the use of Activity Theory. Please take a few minutes to reflect on your experience using the two techniques, and then complete this questionnaire.

1. How did you use each one of the tools to identify the appropriate scope for your need statement?

2. How did you use each one of the tools to come up with context-specific words for your need statement?

3. How well did each one of the tools help you define an appropriate metric?

4. How well did each one of the tools help you define a desired change for your need statement?

5. Do you have any other comments about the two need finding techniques? Please elaborate.

Appendix C Sentiment Analysis Data and Results

The following only has a sample from Question 1 calculations.

C.1 Questions 1 (sample)

Table 6-8 Sentiment Scores for Method A and B for Question 1 (Sample)

	Method A	**Sentiment Score A**	**Method B**	**Sentiment Score B**
1	Method A was more difficult to see where the scope ended.	-0.720	Method B gave some specific scope directly from the contradictions.	**1.41**
2	Did not really, nothing explicitly affected our scope.	0.000	Did not really, nothing explicitly affected our scope.	0
3	Not applicable	0.000	Method B provides a broader description of the problem and I think it helped me determine the scope of the project better.	**0.3**
4	Method A derived the scope from the problem statement.	0.000	Method B derived the scope from the contradictions.	0
5	Method A was more linear – it took me through the steps in a way I already know about. I am comfortable with it and trust it.	0.345	Method B felt a little more disjointed and seemed to focus more on secondary matters but surprisingly also gave a very nice result. I like it as a way to think outside the box.	**0.65**
6	Method A was faster but definitely less detailed scope achieved.	-0.605	Method B has more levels. Takes longer. But able to reach a more detailed scope.	**0.873**
7	Method A: identifying stakeholders then identify cycle of care and flow of money -> find observations/problems-> need statements	0.000	Method B: activity system to break down the idea. The providing the need statement	**0.696**
8	Cycle of care analysis lead to problem identification, inferred scope	0.000	Structured method helped to identify all stakeholders, their roles and the context of the problem, leading to the scope.	**0.548**
9	Not applicable	0.000	Method B was helpful in realizing constraints to include in the statement and to further clarify the statement as necessary	**0.35**
10	Normal – diagram cycle of care lead to problems	0.000	Activity theory – thought about subject, object, instrument and community	0

	Method A	Sentiment Score A	Method B	Sentiment Score B
11	Not applicable	0.000	Activity theory's use of "community" was more useful in identifying scope.	0.792
12	Method A – by identifying the stakeholders and thinking about relevant observations	0.000	Method 2- by specifying the appropriate changes that have to be made	0.483
13	By discussing observations and problems. Then we considered our team background and capabilities and picked the problems that we thought	0.000	By looking at contradictions b/w activities	0
14	Each method was good as they both allowed you to get in very specific details about the project and allowed you to see how each part fits in the big picture.	0.737	Each method was good as they both allowed you to get in very specific details about the project and allowed you to see how each part fits in the big picture.	0.736
15	Conventional need finding helped come up with some main issues and observations easily	**0.445**	The activity theory method helped better identify the various dimensions of the problem involved.	**0.3**
16	Method A allowed us to look at all the stakeholders and the bigger picture to develop a need statement compassing the entire scope.	**0.496**		0
17	Method A was clearer in identifying the scope because you go through the cycle of analysis, you can see the scope directly within the cycle.	**0.300**	Method B was more of a list based system where the scope was somewhat blurry.	**-0.3**
18	For method A, we used the stakeholders and problems that would arise from observing the stakeholders to determine the needs the device should meet.	0.000	For method B (activity theory), we used the activity the device would replace to define the needs statement.	0
19	Identifying stakeholders	0.000	Identifying activities	0

	Method A	Sentiment Score A	Method B	Sentiment Score B
20	Method A analyzed the entire system in one go, whereas	**0.691**	Method B allowed us to define the scope in a more systematic way, analyzing activities separately to determine importance.	0.696
21	No specific way just stated it	0.000	Derived from various components of each activity	0.2
22	The conventional method was used to quickly brainstorm ideas while	**0.645**	Activity theory led us to explore the project more in-depth	1.41
23	Method A identified the scope more through a discussion.	0.000	Method B identified which scope was more important when laying out all the information.	0.696
24	Never really went beyond "the big picture", so the scope was defined from the start.	**-0.300**	Broke the problem down into distinct, separate chunks that could be looked at individually before them all together in the need statement.	**0.498**
25	More focus on identifying the issues clearly to accurately address the needs.	**0.384**	Looking at and analyzing the problem in a system involving number of stakeholders and different aspects of the problem.	**0.3**
26	By reflecting upon stakeholders and their activities, we were able to clarify and identify the purpose of our device and how it will change their current procedures.	**0.300**	By reflecting upon stakeholders and their activities, we were able to clarify and identify the purpose of our device and how it will change their current procedures.	**0.3**
27	The way method A and B linked aspects of the device's design reduced the scope to an appropriate level - from what I originally though would the device's scope.	0.48	The way method A and B linked aspects of the device's design reduced the scope to an appropriate level - from what I originally though would the device's scope.	0.48
28	Brainstorming stakeholders prompted all activities involved in current project environment. Good starting point.	0.519	Brainstorming stakeholders prompted all activities involved in current project environment. Good starting point.	0.519
29	For method A, we made observations and chooses ones that were problems.	0.000	For method B we looked at 2 mains stakeholders and further explored their roles.	**0.3**

	Method A	Sentiment Score A	Method B	Sentiment Score B
30	The conventional tool was a quicker process, but we still reached a conclusion with equal importance.	0.100	The activity theory tool allowed us to break down the "big picture/problem" and target the specific issues present that will overall affect this ultimate design.	0.802

Table 6-9 Question 1 Method B – Detailed Score Breakdown (Sample)

ID	Source Text	Document Sentiment	Phrase	Phrase Sentiment
1	Method B gave some specific scope directly from the contradictions.	1.41	*specific scope*	1.41
3	Method B provides a broader description of the problem and I think it helped me determine the scope of the project better.	0.300	better	0.300
5	Method B felt a little more disjointed and seemed to focus more on secondary matters but surprisingly also gave a very nice result. I like it as a way to think outside the box.	0.65	very nice	0.600
5	Method B felt a little more disjointed and seemed to focus more on secondary matters but surprisingly also gave a very nice result. I like it as a way to think outside the box.	0.65	*outside of box*	0.7
6	Method B has more levels. Takes longer. But able to reach a more detailed scope.	0.873	*more levels*	1.41
6	Method B has more levels. Takes longer. But able to reach a more detailed scope.	0.873	*takes longer*	-0.2
6	Method B has more levels. Takes longer. But able to reach a more detailed scope.	0.873	*detailed scope*	1.41
7	Activity system to break down the idea. The providing the need statement	0.696	*Break down*	0.696
8	Structured method helped to identify all stakeholders, their roles and the context of the problem, leading to the scope.	0.548	helped	0.4
8	Structured method helped to identify all stakeholders, their roles and the context of the problem, leading to the scope.	0.548	*structured method*	0.696
9	Method B was helpful in realizing constraints to include in the statement and to further clarify the statement as necessary	0.35	*Further clarify*	0.3
9	Method B was helpful in realizing constraints to include in the statement and to further clarify the statement as necessary	0.35	helpful	0.400
11	Activity theory’s use of “community” was more useful in identifying scope.	0.792	useful	0.792

ID	Source Text	Document Sentiment	Phrase	Phrase Sentiment
12	Method 2- by specifying the appropriate changes that have to be made	0.483	appropriate changes	0.483
14	Each method was good as they both allowed you to get in very specific details about the project and allowed you to see how each part fits in the big picture.	0.737	specific details	1.41
14	Each method was good as they both allowed you to get in very specific details about the project and allowed you to see how each part fits in the big picture.	0.737	good	0.5
14	Each method was good as they both allowed you to get in very specific details about the project and allowed you to see how each part fits in the big picture.	0.737	big picture	0.300
15	The activity theory method helped better identify the various dimensions of the problem involved.	0.3	better	0.300
15	The activity theory method helped better identify the various dimensions of the problem involved.	0.3	*various dimensions*	0.3
17	Method B was more of a list based system where the scope was somewhat blurry.	-0.3	*somewhat blurry*	-0.3
20	Method B allowed us to define the scope in a more systematic way, analyzing activities separately to determine importance.	0.696	systematic way	0.696
21	Derived from various components of each activity	0.2	various components	0.2
22	Activity theory led us to explore the project more in-depth	1.41	more in-depth	1.41
23	Method B identified which scope was more important when laying out all the information.	0.696	laying out all information	0.696
24	Broke the problem down into distinct, separate chunks that could be looked at individually before bringing them all together in the need statement.	0.498	*"broke the problem down into separate chunks"*	0.696
24	Broke the problem down into distinct, separate chunks that could be looked at individually before them all together in the need statement.	0.498	*"bringing them all together"*	0.3
25	Looking at and analyzing the problem in a system involving number of stakeholders and different aspects of the problem.	0.3	*"Different aspects of the problem"*	0.3
26	By reflecting upon stakeholders and their activities, we were able to clarify and identify the purpose of our device and how it will change their current procedures.	0.3	*clarify*	0.3
27	The way method A and B linked aspects of the	0.480	appropriate	0.480

ID	Source Text	Document Sentiment	Phrase	Phrase Sentiment
	device's design reduced the scope to an appropriate level - from what I originally though would the device's scope.		level	
28	Brainstorming stakeholders prompted all activities involved in current project environment. Good starting point.	0.51880002	brainstorming	0.538
28	Brainstorming stakeholders prompted all activities involved in current project environment. Good starting point.	0.51880002	good	0.5
29	For method B we looked at 2 mains stakeholders and further explored their roles.	0.3	*further explored*	0.3
30	The activity theory tool allowed us to break down the "big picture/problem" and target the specific issues present that will overall affect this ultimate design.	0.802	big picture	0.300
30	The activity theory tool allowed us to break down the "big picture/problem" and target the specific issues present that will overall affect this ultimate design.	0.802	specific issues	1.41
30	The activity theory tool allowed us to break down the "big picture/problem" and target the specific issues present that will overall affect this ultimate design.	0.802	Break down	0.696

Table 6-10 Adjusted sentiment score for Questions 1 (Sample)

Phrase	Adjusted sentiment score	Explanation	
Problem	0	In the context of a design study "problem" refers to the problem space that the design team is handling rather than problem being an issue.	Q1A
Less detailed scope	-1.41	Want to have a negative sentiment - negative of specific detail	
Achieved	0	Achieved does not refer to achievement in this context.	
Conventional	0	Conventional is used in reference to "conventional method".	
Entire scope	0.691	Want to have a positive sentiment	
More clear	0.3	Want to have a positive sentiment - similar to bigger picture	
Helped	0.4	similar to helpful	

Phrase	Adjusted sentiment score	Explanation	
Specific scope	1.41	Same as specific details	Q1B
Broader description	0.3	Same as big picture	
Helped/help	0.4	Same as helpful	
Outside of box	0.7	Self-assigned	
More levels	1.41	Same as specific details	
Takes longer	-0.2	Opposite of quicker	
Detailed scope	1.41	Same as specific details	
Structured method	0.696	Same as systematic way	
Further clarify	0.3	Same as more clear	
Appropriate changes	0.48	Same as appropriate level	
Various dimensions/components	0.3	bigger picture	
Somewhat blurry	-0.3	opposite of more clear	
More in-depth	1.41	Same as specific details	
Laying out information	0.696	Same as systematic way	
"broke the problem down into separate chunks"	0.696	Same as systematic way	
"bringing them all together"	0.3	Same as big picture	
"Different aspects of the problem"	0.3	Same as big picture	
clarify and identify the purpose	0.3	more clear	
further explored	0.3	more clear	
"Further explored"			
"Break down"	0.696	Same as systematic way	
Ultimate	0	Used in the context of "ultimately" and not as the "ultimate" method	
Specific issues	1.41	Same as specific details	

Appendix D Coding Structure

D.1 Design artefacts

Table 6-11 Coding Scheme and Example for Design Artefacts

Name	**Definition**	**Example**
Supply chain	Any references to supply chain and procurement of devices into a specific system (hospital, organization, etc.)	Hospital/procurement
Low-resource setting	Any references to low-resource settings	Low resource setting
System level issues	General code referring to any challenges/conflicts/constraints in a system level - between different stakeholders	Resourceful use of nurses (i.e. unnecessary allocation of manual task)
Access to healthcare	Any ref to access to healthcare services such as challenges with it	No healthcare – access
Environmental	**Any ref to the resources that are available or unavailable - if it does not fit in one of the below categories then it can go into the parent code**	
People	Use this code when there is an explicit reference to a specific stakeholder as a resource. In a sense, all stakeholders are resources. However, I am specifically interested in cases where they are identified as resources and the amount of this resources is referred.	Does not require extra personnel; Resourceful use of nurses (i.e. unnecessary allocation of manual task);
Physical	Use this code when there is an explicit reference to presence or lack of a physical resource.	A certain tool is not available in developing countries. This is a made-up example.
Time	Time is a resource. Code references that hint to lack of time or availability of it. Choose the most specific phrase for this.	Can’t watch patient the whole time, need to put patient into ‘positions’ in order to induce vertigo
Social	**Any ref to aspects of a problem that deals with society - if it does not fit in one of the below categories then it can go into the parent code**	

Name	Definition	Example
Social norms	This code refers to the unspoken social norms in a certain context. It is not referring to a role or job of a person/or an organization. Social norms are different in each culture. For example, in Canada people tend to be polite and say "thank you" or "sorry" more often than someone in NYC.	"Social expectations that you must speak"; - Surgeon wants to treat as many patients as possible
Communication	This code might not be necessary. Most of the references in FG1 and 2 come from verbal communication in FG1 which is heavily dependent on communication because the problem space is that. I want this code to refer to role that communication is playing in any problem space and how much that is explicitly acknowledged.	"Friends and family – communication quality"; "referral to specialist"; any times communication protocols are referenced as part of non-physical instruments
Family and friends	Change this node to "Role of family and friends", family and friends should be selected together as a unit of coding. If they are listed as part of "stakeholder" or "community" then select them independent from other stakeholders. If their role is highlighted in another part of the design artefact select both their role and the words "family" and/or friends.	Family and friends are involved with engagement and support learning; "Family, friends"; "Transport to hospital: ambulance, family and friends "
Economic	**Any ref to aspects of a problem that deal with money and economics of the problem space - if it does not fit in one of the below categories then it can go into the parent code**	
Financial support/funding sources	Financial support for the people	Health care provider is involved with financial support; Government's lack of funding for healthcare cause higher long term costs
Market condition	Competitors and how market is	Little money is available but multiple sources of possible

Name	Definition	Example
		money is available.; competitors
Economically feasible/cost of device	Any references to "is something economically feasible? Or not"	Cost of solutions is too high to be covered.; - BME engineering team and those who made the cheap option
Economic status of buyer/receiver of care	Any ref to economic status buyer of tech or receiver of care through technology	Lots of people cannot afford current option; Economic status of the patient
Political	**Any ref to aspects of a problem that deal with systems and system level issues - if it does not fit in one of the below categories then it can go into the parent code**	
Healthcare provider	Only for "Healthcare provider" phrase	Health care provider is involved with financial support
Non-gov or non-profit organizations	Any ref to NGO and non-profit groups	Scopes provided by donations and international physicians
Government	Any ref to involvement of government	Health Canada and governing bodes
Hospital	Any ref to hospitals	Obtaining proper equipment: hospital
Technology	**Any ref to use, maintenance, etc. of technology - if it does not fit in one of the below categories then it can go into the parent code**	
Quality/reliability of Technology	Description of how quality of a technology should be or is.	
Manufacturing	Any direct references to involvement of manufacturers in development of technology. Do not include any implied or indirect references. Specifically choose only the phrase that only pertains to manufacturing.	Manufacturers; manufacturer does not make cheaper and effective alternative; manufacturers are involved in development of device
Training	This specifically refers to how different users are trained to use the technology. It is not referring to the clinical training that users have. Only select this code if there is an	"Poorly trained nurses might not be able to perform specific pressure application" - only code this to training and design in technology. Do

Name	Definition	Example
	explicit reference to training with the technology.	not code it to "other clinical staff".
Developers	Only refers to stakeholders that are directly involvement in the development of device.	This code is often referring to the engineering team.
Specific instrument	Only select the specific instrument when coding for this node. Do not select the rest of the sentence.	Tourniquet; Scope light
Use	This code only includes cases where there is an explicit mention of how the device is used or should be used.	Using hand pump tourniquet requires attention, annoying for surgeon and nurse
Maintenance	Any direct references to how the device is maintained and who maintains it.	
Technical design requirements	This only refers to technical design requirements. Other aspects are captured through other nodes.	Makeshift tourniquet does not apply desired pressure; must have accuracy +/- 5 degree
Clinical	**Any ref to clinical use and conditions - if it does not fit in one of the below categories then it can go into the parent code**	
Training	Clinical training of professionals/non-professionals	Surgical experience
Medical condition	Any specific medical condition	Patient (with dizziness, possible other ailments).
Physician	If they use the word physician or they are referring to it indirectly	Doctors plan and prescribe
Other clinical staff	Nurses, therapists, etc.	Knowledge of the therapist
Patient	If they use the word patient or they are referring to it indirectly	Patient (with dizziness, possible other ailments).
Legal		
Device Regulation	Only refers to regulations that pertain to use and implementation of technology. Will separate this category.	FDA and medical device regulation
Laws/general regulations	Any reference to general laws and regulations	Malpractice, healthcare regulation

D.2 Questionnaire

Table 6-12 Coding Scheme and Examples for Questionnaire

Code	Definition	Example
Use of Biodesign Method	Code any references that explicitly identify the whole process.	Method A: identifying stakeholders then identify cycle of care and flow of money -> find observations/problems-> need statements
Stakeholder analysis	The role of this code is to extract responses where the participants identifies a way in which stakeholder analysis has contributed to defining need statements. Note that if the responses reference "cycle of care" they are talking about the Biodesign stakeholder analysis.	Method A needs came up during cycle of care; Cycle of care analysis lead to problem identification, inferred scope; Metrics were iteratively inferred from cycle of care and problem statement
Problem statement	The role of this code is to extract responses where the participants identifies a way in which development of problem statement has contributed to defining need statements.	Method A, words came directly from the problem statement.; Method A: each problem statement maps really to a need statement.; Method A: need statement was born out of problem statement. As such problem statement has to be very good for needs statements to capture the problem correctly.
Observations	The role of this code is to extract responses where the participants identifies a way in which development of observations has contributed to defining need statements.	Both methods are good and have their own advantages. Method A – observations/problems
Need statement	The role of this code is to extract responses where the participants identifies a way in which development of need statement helped in achieving greater understanding. This code does not refer to how need statement was developed.	Method A also used the need statement; Both used initial need statement to come up with new changed need.
Use of Activity Theory Method	Code any references that explicitly identify the whole process.	Method B - activity system -> contradictions (this is just an example and is not actually part of the data)

Code	**Definition**	**Example**
Stakeholder Analysis	The role of this code is to extract responses where the participants identifies a way in which stakeholder analysis has contributed to defining need statements.	Stakeholders and context were structurally laid out, so defining relevant metrics was straight forward; Method B was more helpful in defining a need statement based on all the stakeholders' interests.; Activity system but by first identifying stakeholders and then the flow.
Need statement	The role of this code is to extract responses where the participants identifies a way in which development of need statement helped in achieving greater understanding. This code does not refer to how need statement was developed.	Method B, the metric had to be developed afterwards, during the needs statements.; Method B used the initial needs statement; Method B was more helpful in defining a need statement based on all the stakeholders' interests.
Developing activity systems	The role of this code is to extract responses where the participants identifies a way in which development of activity systems has contributed to defining need statements.	Both methods are good and have their own advantages - Method B – activity system breakdown/identifying contradictions; Stakeholders and context were structurally laid out, so defining relevant metrics was straight forward.; Method B: activity system to break down the idea. The providing the need statement
Contradictions	The role of this code is to extract responses where the participants identifies a way in which development of contradictions has contributed to defining need statements.	Contradictions between and within activity systems directly identified needs statement that were specific to the context; Method B: need statement arises from contradictions so it encompasses the entire process of method B.
Familiarity with technique	Use this code if the response indicates that the participant was familiar with the need finding technique or "already knew about it".	It Method A was more linear – it took me through the steps in a way I already know about. I am comfortable with it and trust it.

Code	Definition	Example
Ease of use	Use this code if the response is about how easy it was to apply and use each one of the need finding techniques. Also use this code if the response indicates ease of use with certain part of the technique. Only use this code when there is an explicit reference to ease of use of the technique. For example, "Method A very logical progression between steps that led to specific terms." can be part of structure of analysis but it is not referring to ease of use explicitly.	Method B was significantly easier; Method B considers all the factors as a whole unit and made it easier to find specific works for our need statement
Bringing in stakeholders	This is a thematic node. I want to see where/how theme of bringing in stakeholders/multiple perspectives comes in.	Method B was more helpful in defining a need statement based on all the stakeholders' interests.; Contextually identified through multiple perspectives
Bringing in context	This is a thematic node. I want to see how the theme of incorporating concept is showing up in the questionnaire response. How do the respondents think that the context is being incorporated using each of the techniques?	Method B: Here I used more information. I had to confide most of the elements at once. I think this method might better capture the need if used correctly.; Structured method helped to identify all stakeholders, their roles and the context of the problem, leading to the scope.
Time	Use this code for responses that reference how long it takes to go through each technique	Method A was faster but definitely less detailed scope achieved.; Method B has more levels. Takes longer. But able to reach a more detailed scope.

Code	Definition	Example
Thinking style	Use this code if the participants explicitly identify a specific way in which they are thinking through the problem.	Method B: Here I used more information. I had to confide most of the elements at once. I think this method might better capture the need if used correctly.; Allowed us to think deeper into the problem at hand and be able to identify details we would normally have missed. Going down a hierarchy and by step-by-step allowed us to think deeper; Method B more generic and broad discussion of the problem that led to specific terms.; Method B felt a little more disjointed and seemed to focus more on secondary matters but surprisingly also gave a very nice result. I like it as a way to think outside the box. Perhaps Method B led to more appropriate metrics since the approach was more broad and implicitly extended the thought process.
Structure of analysis	This code refers to the overall structure and steps that the participants follow for this need analysis. This is the structure that they have explicitly identified through their reflection. There is an innate structure for both of the methods but theme specifically looks at how each person interpreted the structure and what type of structure they created for themselves.	Method B, words came from the contradictions. Method B felt harder to work through, as the concepts were broader and possibly more abstract. However, they may have resulted in “better” outcomes.; Allowed us to think deeper into the problem at hand and be able to identify details we would normally have missed. Going down a hierarchy and by step-by-step allowed us to think deeper.

Code	Definition	Example
Level of analysis	This code refers to responses about depth understanding they achieved; when responses mention less or more scope achieved and when a good overview is provided.	Method A was faster but definitely less detailed scope achieved.; Method B has more levels. Takes longer. But able to reach a more detailed scope. Perhaps Method B led to more appropriate metrics since the approach was broader and implicitly extended the thought process.
Use of previous knowledge	Code any references to use of previous knowledge in the analysis - Use of any	We used previous knowledge to develop need statement (This is just an example and it is not actually part of the data set)
General feedback about workshop	Any general feedback about the quality of the workshop and participant's experience.	The workshop was helpful. (This is just an example and it is not actually part of the data set)

Appendix E Follow-up interview ethics application

E.1 Consent form

a place of mind

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Consent Form
Need Finding Technique based on Activity Theory Sub-study
Follow-up Interview

Principal Investigator:
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Co-Investigator:
Florin Gheorghe, M.A.Sc. Candidate
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Purpose:
The purpose of this study is to examine the experiences of student design teams as they are going through their project's needs assessment phase and to test various design methods of need-finding that can lead to better formulations of design needs of new devices. The research will explore how using these strategies could improve the capacity for innovative ideas and identifying latent needs for various clients in the domain of medical and personal-use device. This sub-study is part of the M.A.Sc. thesis of Shalaleh Rismani, who is the only co-investigator that is currently involved with this sub-study.

Study Procedures:
The research will be qualitative in nature, focusing on the student design teams that are currently enrolled in the Engineers-in-Scrubs program, the New Venture Design course, CPSC 444, and other design based courses at University of British Columbia. In addition, members of the Biomedical Engineering Student Team are invited to participate in the study as well.

The research team will conduct a semi-structured follow-up group interview with design teams that took part of the original sub-study. The interview will take no longer than 90 minutes. During the interview the team will start by participating in structured activity and then a series of questions will be asked from the team based on their activity. Recording of sessions may take place.

Potential Risks:
The physical, emotional or psychological risks associated with this sub-study are minimal. The participants will only participate in a facilitated need finding workshop and will be asked questions about their project.

Potential Benefits:
Participants could benefit from learning about design strategies to increase their capacity for expressing innovative ideas and approaches in their work. An indirect benefit is that the outcomes of this research will inform the development of innovative technology.

Confidentiality:
All data will be kept in a locked cabinet, and computer files password protected. Participants will not be identified by name in any reports of the completed study; only the research team will have access to this information. Participants are able to seek attribution if they wish to do so. The research team will ensure to protect the privacy of the participants; however, it is important to acknowledge that the ability to guarantee confidentiality in a focus group is limited.

Contact for information about the study:
If you have any questions or desire further information with respect to this study, you may contact Shalaleh Rismani.

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without jeopardy to your work or participation in any future design oriented activities. The decision to participate or not to participate will have no impact on your academic program.

Initial here if you are providing consent for interview/focus group discussion ___________

Initial here if you are providing consent for photography / audio / video (circle one or all) recording:

____

Your signature below indicates that you have received a copy of this consent form for your own records.
Your signature indicates that you consent to participate in this study.

____

Subject Name (print) Signature

____

Date

In addition and separately, I agree to allow my comments to be quoted in reports or publications. If a quote were used, there would be nothing in the quote that could identify me, or any of my clients.

____

Subject Name (print) Signature

____________________ Date

E.2 Group Interview Protocol

Focus Group Protocol
Need Finding Technique based on Activity Theory Sub-study
Follow-up Interview

Consent Process
Thank you for reading and signing the Human Subjects Consent Form for this project entitled "Need Finding Technique Based on Activity Theory Sub-study: Follow-up Interview".

Introduction
Thank you for agreeing to take part in this follow-up study. My name is _________________________ and I will be facilitating today's group discussion. I am a research assistant working with Dr. Mike Van der Loos, who is an Associate Professor in the Department of Mechanical Engineering of the Faculty of Applied Science at the University of British Columbia.

We have invited you to take part in this workshop today because you took part in an earlier focus group and we wanted to follow-up with regards to some of the outcomes.

Today I am playing two roles: that of a facilitator and that of a researcher. This means that I will facilitate this workshop, while at the same time I am trying to test and evaluate the design process itself.
At this time I would like to give a brief overview of the session. [5min]

Ground Rules of Discussion

I am going to facilitate your group through one need-finding activity. Following that I will ask a number of questions in form of a semi-structured group interview. A framework will be provided for these activities. There is not a particular way to engage with these activities but we do want everyone to take part in the discussion as your ideas are all important to our research.

This workshop will include a lot of team discussion. Feel free to treat this as a discussion and respond to what others are saying, whether you agree or disagree. We're interested in how you engage in these activities based on your own understanding of the instructions. There is no right or wrong answer. We are here to learn from you.

Please do respect each other's answers and opinions during the workshop. We ask that only one person speak at a time.

We will treat your team discussion in the workshop as confidential. We are not going to ask for anything that could identify you and we are only going to use first names during the workshop. We also ask that each of you respect the privacy of everyone in the room and not share or repeat what is said here in any way that could identify anyone in the room.

We are video and audio-recording the workshop today and also taking notes because we don't want to miss any of your comments. Once we start the video and tape recorder, we will not use anyone's full name and we ask that you do the same.

We will not include your names or any other information that could identify you in any reports that we write. We will destroy the notes, videotapes and audiotapes after we complete our study and publish results.

Finally, this workshop is going to take about 90min. You are free to leave at any time, though we would prefer if you stay for the whole time.

Does anyone have any questions before we start?
[Start tape and video recorder]

Instructions for Participants:

You will be asked to complete one need finding exercises on your course project. Please feel free to use the necessary whiteboard space and necessary tools to complete the tasks.

Definition of terms:

Observations – The data and information that the design team gathers from their research
Stakeholder – All the individuals and organizations involved with the project
Problem statement – Inadequacies or limitations derived from observations on the project
Need statement – A statement that identifies a necessary change and it includes a metric
Activity Theory – Cultural-historical psychology theory describing the relationship between humans and the tools they use to reach their objectives
Activity system – A triangular framework that connects the elements of an activity – subject, object, instrument, community, rules and division of labour.
Contradictions – Inconsistencies and tension points in an activity system or between activity systems
Need finding – The process of defining needs in a product development firm

Part A: Activity Theory Based Need Finding (45 min)

In this section you will be asked to complete a need finding exercise based on Activity Theory.

Task 1: Identifying activity systems

From your stakeholder analysis pick 2-3 major activity systems that you would like to analyze in this activity. Define the activity systems by defining the following: subject (i.e. your stakeholder), object, outcome and time of the activity. Refer to the activity system hand-out for the definition of each one of these terms.

Task 2: Developing activity systems

Based on the questions in the activity system hand-out define the three activity systems in full detail. Write out the answers to these questions in full and concise sentences in the appropriate section.

Task 3: Identifying contradictions

Now that you have your activity systems identify contradictions within or between the three activities. Describe the contradictions using the following format:

Type of contradiction (i.e. between two elements of one activity, between elements of two activities)	

The contradicting elements	
Description (**What** is the contradiction? **Where/when** is it taking place? **Why** does it exist? **How** can it be resolved?)	

Task 4: Developing need statements from contradictions

The final task is to convert your contradictions to need statements using the following the questions:

4. Identify what needs to be changed for the contradiction to be resolved.
5. Identify a few key metrics based on the activity network for that change.
6. Write a need statement that is verifiable and has a specific scope. The need statement should identify a desired change and have a few key metrics.

Part B: Semi-structured Interview (30 min)

Following the activity the teams will participate in a semi-structured group interview. The following is the interview question guide.

1. What is your opinion about the terminology that is used in this technique (i.e., activity, elements, subject, object, division of labour, rule, etc.)? How easy is it to understand them? Which terms are clearer in definition? Which ones are more vague?
2. When constructing activity systems, which elements are easier to develop? Which are more difficult to develop? Why?
3. What do you think of the following two elements: rules and division of labour? Are they intuitive to develop? How do you think they assist you in understanding the problem space? What are your thoughts about separating technical and non-technical points in these elements?
4. How difficult is the process of going from contradictions to needs? Is it intuitive? Is it challenging?
5. What are some of the advantages of this technique?
6. What are some of the limitations of this technique?
7. Would you use Activity Theory based needs finding again? Why? If not, why not?

Thank you very much for your time and for sharing your opinions with us

We look forward to coming back to share with you the results of this study. Do you have any advice for us before we conclude for today?

Protocol for Observation of the Focus Group

The facilitator will also play the role of an observer when the student teams are using the need finding techniques.

The intended goals for observation are:

- To gain insights on challenges faced by the teams when they are using they two techniques
- To conduct an ethnographic analysis of use of these two techniques

The facilitator will specifically be looking at the following aspects of need finding phase throughout the observation period:

- What are the roles and interactions of various team members?
- How much time do the teams spend on the various parts of each task?
- What difficulties, constraints, and challenges arise as a result of use of the two techniques?
- What adaptations and moment-to-moment improvisations in practice are the design teams making in order to adapt to the challenges?

The observing researcher will not be collecting any identifying information about the procedure aside from a general explanation of what type of procedure is being performed/. No identifying information will be collected on any of the participants under the observation.

All the participants will be asked to sign a consent form for observation.

Appendix F Follow-up interview data and results

F.1 Images of the design artefacts

Interview 1

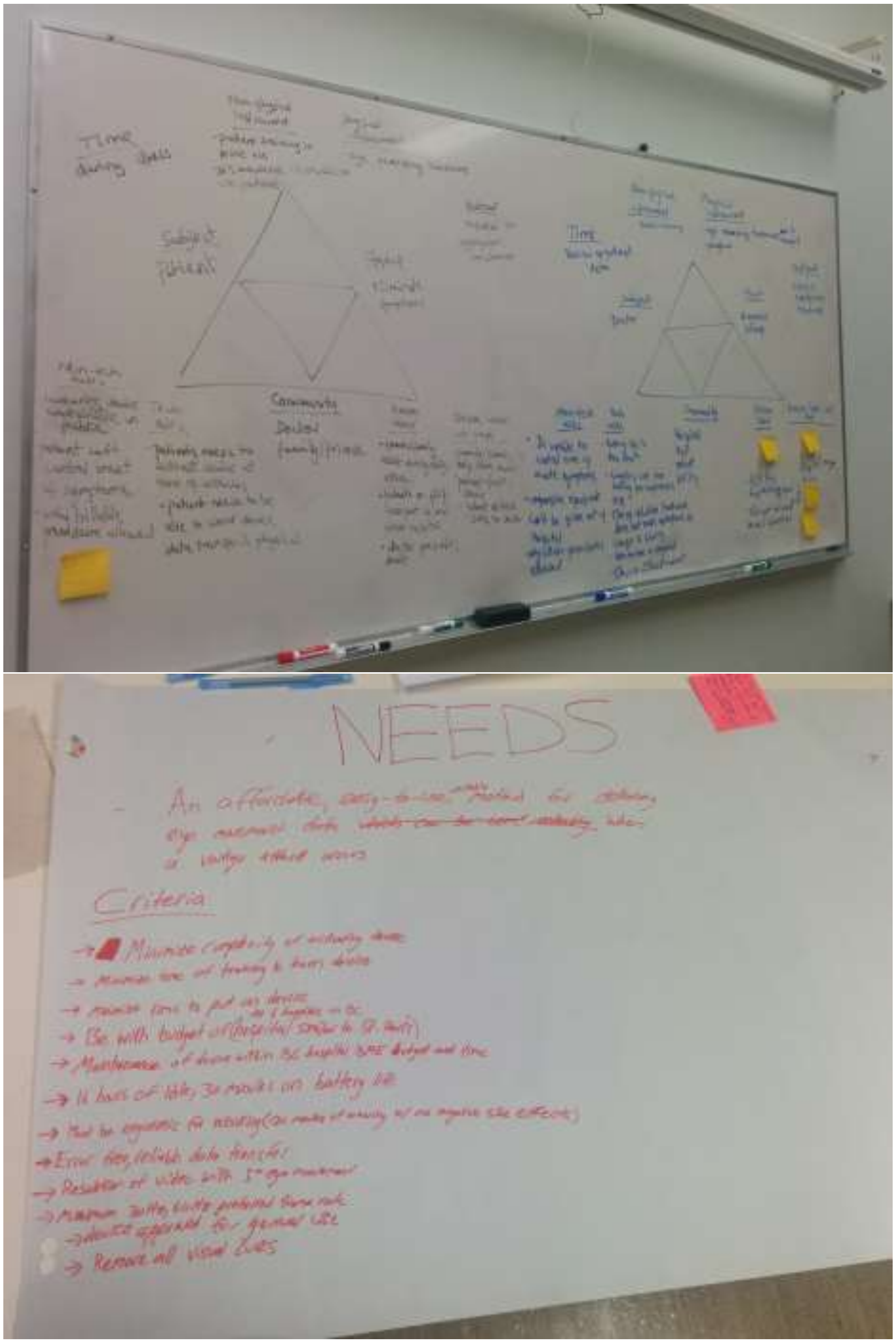

Figure 6-15 Design Artefact from Follow-up Interview #1

Interview 2

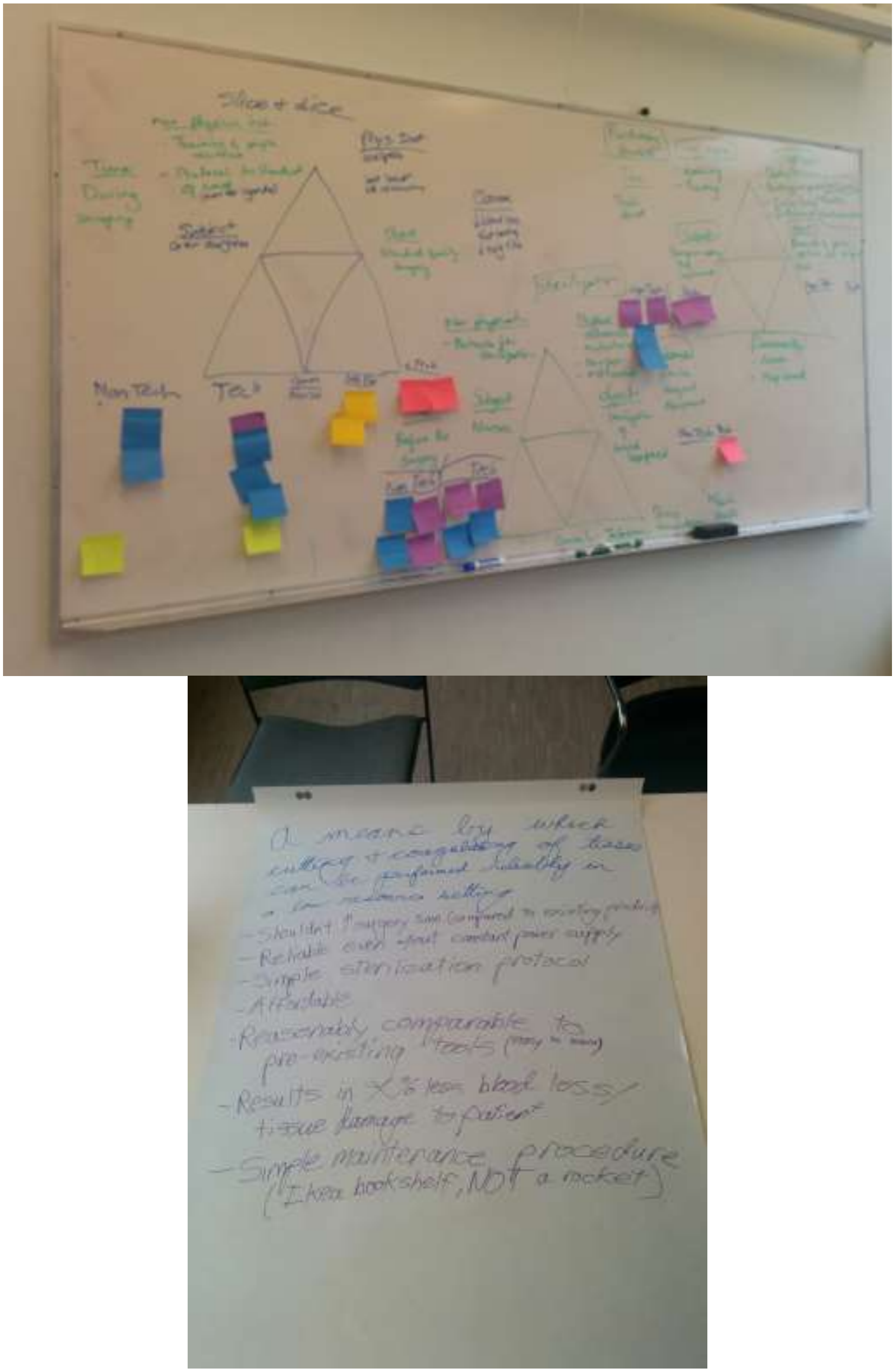

Figure 6-16 Design Artefact from Follow-up Interview #2

Interview 3

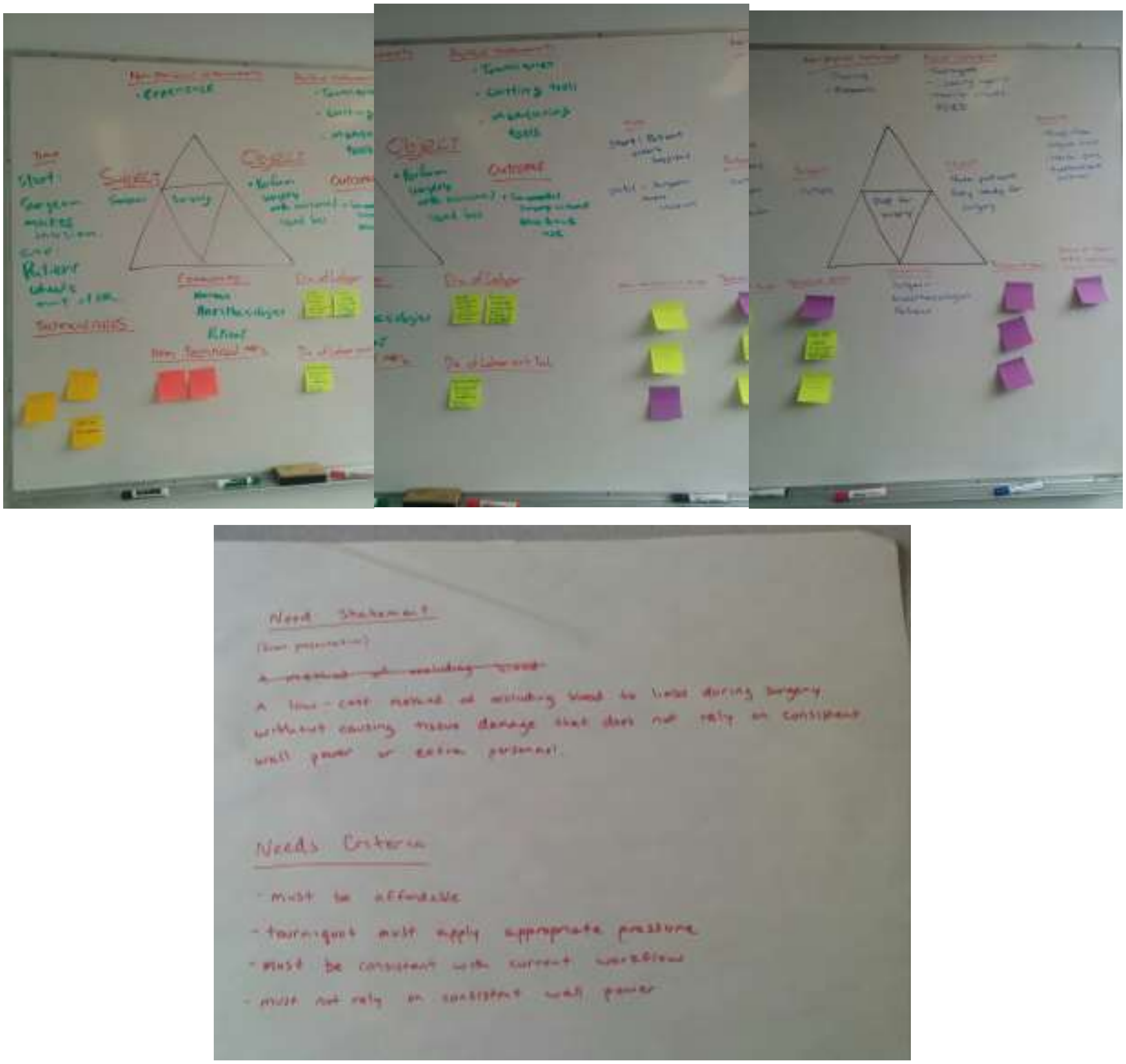

Figure 6-17 Design Artefact from Follow-up Interview #3

F.2 Interview transcripts

Interview 1

Q: What are your overall thoughts and general impressions about the ATNF method?

P1: I can't think of a good exact but going through this I thought it was clear what I am doing will impact the overall outcome. But I like it a) because it is holistic b) it is a lot easier to justify my choices based on this. I can see a lot of things. I just said this XYZ requirement but that is because of all of this right there.

P2: what I am liking now. We got all of our requirements from our non-technical rules and tech rules. It makes some stuff easier just because of the holistic nature and looking at the entire problem. It actually gives us information that we will need later on.

P3. It made it easy I wouldn't know about easier. The other technique I am more familiar with. I agree with p1 that this one was holistic but it was also hard especially with type of training that we have had thinking about division of labour with respect to technology versus division of labour

P4. I feel like it is less likely we will miss something. It feels bigger. The other method is whatever comes to your mind and you throw it down. Hopefully you have thought about everything. For simple things you can do that easily.

P5. It forces you to consider all the factors

P1. My critique here is that I don't think we used any of the instruments. I am looking at it and trying to see did we consider that but I don't think we did that. I feel like we focused on the bottom half entirely. Subject and object it is clear we need to have it there. But instrument physical and non-physical we didn't really use it.

P3. I really liked that we started with stakeholders and did activities and activity systems for different stakeholders. I thought that was a really good tool for not missing things. I certainly wasn't doing that in my analysis before and that really made us put our different hats and try to be this individual stakeholder.

Q: Which one of the terminologies were easy to understand or difficult to understand? And how could that be made easier?

P3. I say that the term activity systems it confused me the first time and even learning it a week or two ago, when you said we have to do activity systems, I was like oh what is that and then I looked at the framework and I said it is the triangle with all the things. I don't know if it clear immediately.

P2. Triangular framework could work out well.

P1. For me everything worked out pretty well. Maybe rules, because I don't feel like those are rules. They are constraints and way things are done. I was thinking what are the rules we have to satisfy - for example it has to be portable. But these are also existing constraints for example we have to have physical data transfer. Boundaries.

P2. Now that I think about it we didn't actually consider the instrument at the end but I think instrument gives you a little bit of play when you are coming up with constraints. For example, your battery life is too short comes from the fact that you are recording stuff. The fact that the data transfer is physical comes from the playback.

P1. For me that came from the original proposal.

P3. It is sometimes challenging not to think of the now and not potential ideas when thinking about instrument.

P1. It would be good to clarify for time that we are looking at the current state. Because you could also look at the future.

P3. I am not sure if this has to be in the time box but I definitely think it should be in the overall theme of the technique.

P3 time refers to a specific timeframe that is when patient is using X or when physician is doing X. It is good identify that we are looking at existing activity overall.

Q. What do you think about separating the nontechnical and technical components?

P1. I like it. Because there is a nice contrast. It is easy to fill out the technical rules because you have a bunch but then you don't get the address that the doctor is unable to control the time for acute symptoms which is literally one of the major problems they literally can't do it. It just wouldn't fall under technical rule. For someone who is very technical like myself, it is nice to have this separation because it forces me to fill out something for it.

P2. The only place I didn't find it useful was for division of labor. I thought it was very useful for instrument and with constraints. Maybe it is just for this project but Division of Labour doesn't seem to be too different

P1. Could see what P2 meant.

P3. Thought it was useful. Doctor looking at the data is important.

P2. It was hard to sometimes define and distinguish technical/non-technical. There is a gray areas

Q. What did you think of contradictions? Does it help find needs?

P4. I don't know the word contradictions but in my mind conflict, where are there competing interests, trade-off

P1. Conflict is better than trade-off. Because it says there is an issue with x and y and it needs to be addressed.

P1. Think it helps find needs quite well.

P3. There could be a more structured approach for helping to see where to look for contradictions. Looking at it as a whole for us wasn't so bad because we had two systems. I can see more structure could help. I thou finding contradictions was slightly more challenging than brainstorming ideas.

Q. Do you have any other comments, criticism and ideas?

P4. Would it be useful to have an input similar to output? Why does the patient have to go to get care? It would be more symmetric. That would be nice. Why is the subject in this situation? Will it be useful for need statement finding? It does tell us about pathophysiology and disease state. It raises good questions about the state of the patient. Your input should be physiology. It would have the same role of instruments - it would anchor discussion. Input could be difficult diagnosis, patient with unknown issue, patient with a known diagnosis.

Q. Is this a technique that you might want to use?

P2. Two conditions. If I am in a more traditional setting and I find myself stuck.in how I am thinking about the problem, I would find myself use this. If I am in a really unknown situation, I would use this two because it forces me to know more things.

P1. Could use it to develop questions. Really assess how much do you know or not know.

P3. The other technique is easier to use and we know it better. We used it in the other two projects. This was probably more comprehensive but it harder to use. Having done this twice I see a lot of value in the technique.

P4. It helps a lot. I find it easy to remember the structure. I think I already remember. Two triangles one inside each other.

Interview 2

Q. What are your initial impressions of the ATNF technique?

P1. It is different from the normal way we use, it was very hard, especially in the first session, to understand what we are trying to. There was a steep learning curve. I understand more now but it is a dissociative thing where I have to think about how I have been thinking about it and then think about how I can fit those things into this process instead of the way around.

P2. Maybe some way of direct association with the previous linear method would be helpful. Because that was in sequence and this in parallel. It is a different paradigm. Figuring out combining. They each have their advantages. In the first one thinking linearly is helpful. In this one you have to think about contradictions, rules, different boxes.

P1. Another thing we struggled with is lack of specifics because this lends itself to specifics and data and stat. We do not know any of that.

P2. We haven't talked to enough clinicians to get the data. It is data dependent.

P1. It feels early for me to know that stuff but we might be the lazy group.

Q. Do you think doing it early in the process can guide you in different directions?

P2. Yes, we came up with few questions that we definitely want to ask people. Blood loss, how much time.

P1. There is a sweet spot in terms of when to do it. The first time they did it they knew even less. At this point in the process (2nd time) it was more helpful.

P1 and 2. It would be good to take this all data and punch it into a computer program. Say I have blanks here, here and here. When know them we can put it into appropriate stuff.

P2. Nodes in graph theory - connection to that theory. Definitely you can develop a computer program to capture this technique and data.

P1. I like how this makes you draw and the computer thing would be after this. Because this is a great way for you to visualize all the different aspects.

P2. It is good for visual learners.

P1. The division of labour and the physical artefacts allowed us to see what everyone is thinking and we need more information for a certain aspect.

Q. What about the terminology?

P1. We were definitely confused about object and outcome. Object came because you have subject. Is it the object or the objective? Is the outcome positive manifestation of the objective? Is it always tied to the objective?

P2. What fits into technical and non-technical. There is not a clear description. Rules are not always rules. Maybe procedures.

P1. I had trouble with division of labour and Division of Labour with respect to tech.
P2. Subject, community and division of labour make sense.

Q. Have steps for what you have to do first.

P2. I struggled with how comprehensive. We need to be. For surgery who is in the community? What is community and would should stay out.

Q. What did you think of contradictions?

P1. It wasn't intuitive. It is difficult to visualize contradictions. What is the definition of contradictions?

P2. What is your understanding contradictions? Any two piece of information that don't go with each other. I was thinking about it literally. They don't have power but they don't have power. Some contradictions are obvious. Examples of contradictions would be helpful.

Q. Is there an element you would take or add?

P1. The actual defining of the activity was subjective. Which activities should we look at it? How can we split the activities? It can be more structured for choosing which activities.

Q. Would you use this again?

P1. First course I have used a structured process so I am not sure if I would use this. This is the first time I have done this.

P2. If I got good at it I would like it. It could be good for start-ups and businesses.

P1. Being proficient would be nice.

Interview 3

Q. What are your initial impressions about ATNF?

P1. The word rules makes it difficult to come up with content for that category. Different title would be easier. Because when I think of rules I think of written rules but these are not the things that go into that category. When I think about it" as a rule this happens..." Makes it easier

P2. It was nice to further develop few things that we knew implicitly. It is good to keep those in mind. I never thought about some factors.

P3. I think in order for this to be useful session you need a facilitator. Among ourselves it is not natural to say we can do this. You need a dedicated person in the team to be a facilitator. It wouldn't work if everyone was just sitting down and brainstorming.

Q. What part of the process are natural or harder to understand?

P3. It was hard to understand object vs outcome because they are so interconnected. It can be helpful depending on the activity.

Other terminology that is confusing?

P4. Non-physical instrument is hard to understand. Instrument is always tangible. Hard to wrap my head around. Maybe tools would be better. It is a category that we don't really use it. I am not sure if it is not useful or we could not use it.

P2. We were dependent on the current example. We have to rely on the example to facilitate our thinking. More intuitive title for the categories.

Q. What is your opinion about technical vs. non-technical? Is the line blurry?

P1. It is less blurry with division of labour. But more so with rule.

Q. Advantages and disadvantages of this technique

P4. I really appreciate this technique because we always think of one path. It helps us to think outside of the box and organizes our thoughts and allows us to branch out from there
The structure could potentially take some freedom away from the implementation

P2. Good thing and a bad thing because it makes it look at it more holistically so sometimes it is too general and not specific.

Q. Do you think that should be added or taken away?

P1. Contradictions was helpful.

F.3 Thematic analysis

The following describes the major themes that were observed in the follow-up interviews:

- ATNF is a holistic and comprehensive approach. It provided means of justifying decisions.
- ATNF allowed for development of questions.
- ATNF has a steep learning curve. More proficiency would help with application of the technique.
- Challenges with terminology:
    - The division between non-technical and technical elements can sometimes be unclear.
    - The term rules does not match its prompt questions. A preferred term would constraints or conditions.
    - The term contradiction is not completely intuitive. A preferred term would be tensions or conflict.
    - The difference between objective and outcome is unclear
- Suggestion for improvements
    - Have another box for "input" which would describe the state of the elements of the activity system prior to the activity.
    - Create a computerized program that would allow design teams to capture and update activity systems over time.
    - Improvement in the terminology and a more clear list of prompt questions